**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

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| LOUISIANA HEALTH SERVICE & INDEMNITY COMPANY D/B/A BLUE CROSS AND BLUE SHIELD OF LOUISIANA, HMO LOUISIANA, INC., and DAVID MITCHELL, individually and on behalf of all others similarly situated,<br><br>Plaintiffs,<br><br>v.<br><br>CELGENE CORPORATION, BRISTOL MYERS SQUIBB COMPANY, ANTHONY INSOGNA, and JEROME ZELDIS,<br><br>Defendants. | Case No. 1:23-cv-07871<br><br>[redacted] |

**MEMORANDUM OF LAW IN SUPPORT OF**
**DEFENDANTS CELGENE CORPORATION AND**
**BRISTOL MYERS SQUIBB COMPANY'S MOTION TO DISMISS**

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In February 2013, Celgene[1] won FDA approval for Pomalyst®, an essential drug for the treatment of multiple myeloma, following massive investment in clinical research and pharmaceutical development. For its innovative work, the Patent and Trademark Office (PTO) awarded Celgene nine patents related to Pomalyst: patents covering methods of using pomalidomide (Pomalyst's active ingredient) to treat multiple myeloma (the '262, '428, and '3939 patents), expiring by 2025; patents covering oral dosage forms (the '427, '467, and '5939 patents), expiring by 2031; and patents covering different crystalline forms, or "polymorphs," of pomalidomide (the '647, '648, and '649 patents), expiring by 2037.[2] Backed by this intellectual property, Pomalyst has been instrumental in the treatment of countless patients who are able to live longer, healthier lives with this disease.

The Pomalyst patents, the first of which was filed for in 2008, issued by the PTO between 2012 and 2020, following examinations of the claimed inventions by PTO examiners. Years later, Plaintiffs now claim to have uncovered what no one—including the PTO and the nine generic manufacturers against whom Celgene litigated these very patents—has ever found: a sweeping "scheme" purportedly spanning fifteen years to *defraud* the PTO and bring patent infringement suits against generic manufacturers that were not just meritless, but "*shams*," all in an alleged effort to monopolize. Plaintiffs claim to have found evidence of this scheme not in secret documents or private records or the testimony of some whistleblower, but in the pages of patent prosecution files accessible to the public, and to the generics who litigated against Celgene, for years.

[1] Defendants Celgene Corporation and Bristol Myers Squibb Company are described collectively as "Celgene."

[2] To track the Amended Complaint, we refer to each patent by the last three digits of its patent number (except for the '3939 and '5939, referred to by four digits to distinguish them). We also refer to patent applications by their eventual issued patent number, rather than by application number.

But Plaintiffs' claims that the patent litigations were "shams" ring especially hollow against the fact that the generics settled in 2020-2021 for patent licenses commencing in 2026. Casting about for an explanation of why the generics—putative competitors of Celgene's and one-time defendants in this antitrust suit (before Plaintiffs voluntarily dismissed them from the case)—would agree to such settlements if the patents were all worthless "frauds," Plaintiffs divine another theory: the settlements must have been tainted with multi-hundred-million-dollar "payoffs." But Plaintiffs' lack of any cognizable basis to circumvent Celgene's patent rights does not give them license to conjure baseless claims about astronomical payoffs hidden in the terms of settlement agreements. The settlements contain no such payments; like the patents themselves, the settlements are lawful.

Despite two tries, Plaintiffs have come nowhere near meeting their burden to plead plausible allegations sufficient to seek antitrust treble damages, and their claims should be dismissed.[3]

## BACKGROUND

### I. Patent Prosecution.

Most of Plaintiffs' fire is trained on Celgene's interactions before the PTO in prosecuting its patents. As with all patents, Celgene started by filing a patent application consisting of a specification that contained the "written description of [its] invention," and ending with claims that "particularly point[ed] out and distinctly claim[ed] the subject matter which [Celgene] . . .

[3] Plaintiffs' Counts I and II arise from the challenges to the patent settlements (*see* Am. Compl. ¶¶ 406, 420); Counts IV and V from the issuance and assertion of the patents (*see id.* ¶¶ 431, 450); and Counts III and VI are catch-all claims under "consumer protection" statutes and common law (*see id.* ¶¶ 428, 475). Finally, Counts I and IV assert federal law injunctive relief claims. Plaintiffs' damages claims are asserted not under federal law, given that Plaintiffs are not direct purchasers, but under the law of various (at least 28 different) states. While many of those state laws are inapplicable, those issues are beyond the scope of this motion, under which all claims fail together for the reasons set forth herein. *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 139 (E.D.N.Y. 2003) ("[S]ince Plaintiffs fail to state a claim under the Sherman Act, and since the state antitrust law claims are based on the same allegations, those claims are also dismissed."); *In re Humira Antitrust Litig.*, 465 F. Supp. 3d 811, 847 (N.D. Ill. 2020).

regard[ed] as the invention." 35 U.S.C. § 112(a)-(b). During prosecution, Celgene also provided to the patent examiner numerous "Information Disclosure Statements," that listed "patents, publications, applications, or other information submitted for consideration." 37 C.F.R. § 1.98(a)(1). Patentees are not required to disclose information that "is not material to the patentability of [a] claim," or to disclose information that is "cumulative to information already of record." *Id.* § 1.56(a)-(b).[4] The examiner then applies their scientific background to evaluate the record—including conducting his or her own searches—to determine which claims of the patent should issue. *See* Manual of Patent Examining Procedure § 904.02 (explaining that during an examination of an application, an "examiner must conduct a thorough and complete search of the prior art").

In the course of prosecuting the nine patents here, Celgene disclosed *hundreds* of sources—domestic and foreign issued patents, patent applications, scientific studies, and press releases alike. As is almost invariably the case in patent prosecutions, Celgene's applications were often initially rejected over prior art. These interim rejections were not the end of the road—rather, Celgene was invited to "reply" to them by "point[ing] out the supposed errors" therein and "reply[ing] to every ground of objection and rejection." 37 C.F.R. § 1.111(b). Celgene could also "amend[ its claims] in reply" by "show[ing] how the amendments avoid[ed] such references or objections." *Id.* § 1.111(c).

[4] *Inequitable conduct* is an affirmative defense to a claim of patent infringement that can render the patent unenforceable. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285, 1290-91 (Fed. Cir. 2011). It requires proof, by clear and convincing evidence, that during the prosecution of a patent, the patent applicant misrepresented or withheld material information from the PTO with a specific intent to deceive. *Id.* "[T]he showing required for proving inequitable conduct and the showing required for proving the fraud component of *Walker Process* liability"—what Plaintiffs here plead—"may be nearly identical." *TransWeb, LLC v. 3M Innovative Properties Co.*, 812 F.3d 1295, 1307 (Fed. Cir. 2016). If Plaintiffs have not adequately pleaded inequitable conduct (and they have not), they likewise have not adequately pleaded *Walker Process* fraud.

This iterative process—Celgene's applications and disclosures, and the examiner's own searches, followed by rejections, responses, amendments, and more disclosures—took years. It was all memorialized in a public prosecution history documenting each representation Celgene made, and each decision the examiners made. Ultimately, each examiner, satisfied that Celgene had demonstrated that certain patent claims were novel over the prior art, issued those claims. It is because the PTO "examined whether the patent[s] satisfie[d] the prerequisites for issuance," that Congress mandates that such patents are "presumptively valid," *Cellspin Soft, Inc. v. Fitbit, Inc.*, 927 F.3d 1306, 1319 (Fed. Cir. 2019) (cleaned up); *see* 35 U.S.C. § 282(a), and why, in a patent infringement suit, it would require "clear and convincing evidence" to invalidate them, *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018).

## II. The Hatch-Waxman Act Framework.

The Hatch-Waxman Act sets forth a carefully choreographed set of steps for patent litigation between brand name drug manufacturers and generics that is designed to balance incentives so that (i) innovators continue to invest in new treatments in exchange for patent protections; and (ii) generics have a pathway to introduce competing products into the market. *See* Am. Compl. ¶¶ 23-24; *see also Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370-71 (Fed. Cir. 2002) (explaining this framework).

Celgene submitted a New Drug Application (NDA) to the FDA for Pomalyst in 2012. Am. Compl. ¶¶ 198-99. Because Celgene was the first company to secure FDA approval for a pomalidomide product, in 2013, it was granted a five-year exclusivity until 2018—New Chemical Entity exclusivity—apart from, but concurrent with, patent protection. *Id.* ¶¶ 26, 199-200. Upon receiving FDA approval, and as required by the Hatch-Waxman Act, Celgene began submitting its pomalidomide patents to the FDA for listing in the "Orange Book," which reflects the patents claiming the brand products or methods of using the same that "could reasonably be enforced

against a generic manufacturer" looking to sell a generic of that product.[5] *Id.* ¶ 18; 21 U.S.C. § 355(b)(1)(A)(viii).

Ultimately, nine generics filed Abbreviated New Drug Applications (ANDAs) to sell generic pomalidomide, under which they "piggyback[ed] on the safety-and-effectiveness information that" Celgene had submitted to the FDA for Pomalyst. *In re Rivastigmine Pat. Litig.*, 2005 WL 957426, at *1 (S.D.N.Y. Apr. 25, 2005). Six generics[6] filed on the first available day, and thus shared first-filer "exclusivity," entitling each of them to 180 days of exclusivity from later-filer generics. Am. Compl. ¶ 32.

Each generic also submitted to the FDA and sent to Celgene what is known as a "Paragraph IV" certification, stating that, "in [its] opinion," Celgene's Orange Book-listed patents "[are] invalid or will not be infringed by the manufacture, use, or sale" of the proposed ANDA products. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); Am. Compl. ¶ 29. A Paragraph IV certification is not a finding of patent invalidity or non-infringement—it is an assertion by the generic, sufficient to trigger federal subject matter jurisdiction over an action for patent infringement filed by the patentee. *See* 35 U.S.C. § 271(e)(2). Upon receipt of notice of the certification, Celgene had 45 days to sue in order to ensure resolution of its patent infringement claims prior to any launch of the generic. 21 U.S.C. § 355(j)(5)(B)(iii). So long as Celgene moved quickly to protect its patent rights by filing suit, the Hatch-Waxman framework imposes a thirty-month stay on the FDA's approval of the generic's ANDA, in order to allow for the orderly resolution of the patent litigation. *Id.*

Here, Celgene and the nine generics proceeded to patent litigation in the District of New

[5] Celgene submitted six of the nine pomalidomide patents to the Orange Book; the remaining three patents, on polymorphs, were not required (or permitted) to be listed because they do not cover Pomalyst itself. *See Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1343-44 (Fed. Cir. 2003).

[6] Though Par Pharmaceuticals was a seventh first-filer, *see* Am. Compl. ¶ 247, "Par withdrew its paragraph IV certification early on, leaving 6" first-filers, *id.* ¶ 343 n.100.

Jersey. *See, e.g.*, *Celgene Corp. v. Hetero Labs Ltd.*, 17-cv-3387 (D.N.J.). After almost five years of litigation, these cases eventually settled, allowing generics to enter the market by 2026, five years before the last of the Orange Book-listed patents for Pomalyst expire in 2031. *E.g.*, Am. Compl. ¶ 313. Such settlements are typically confidential, but by statute are provided to the FTC and DOJ. *See* Section I.C.4, *infra*. Plaintiffs now bring this lawsuit alleging that Celgene's conduct was unlawful, decades after these patents were prosecuted, a decade after FDA approval for Pomalyst, and years after Celgene and generic companies settled patent disputes that largely respected Celgene's patent rights, but also allowed for generic entry prior to the last-to-expire patents.

## LEGAL STANDARD

Given the "unusually high cost of discovery in antitrust cases," courts require plaintiffs to plead more than conclusory allegations in order to avoid the "potentially enormous expense" of litigating "largely groundless claim[s]." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558-59 (2007); *see also City of Pontiac Police & Fire Ret. Sys. v. BNP Paribas Sec. Corp.*, 92 F.4th 381, 391 n.1 (2d Cir. 2024) (observing in an antitrust case that courts "retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed").

## ARGUMENT

### I. PLAINTIFFS FAIL TO PLAUSIBLY PLEAD AN ANTICOMPETITIVE REVERSE PAYMENT IN ANY SETTLEMENT THEY CHALLENGE.

Plaintiffs' challenge as to the patent litigation settlements centers on three of the first-filer generics. Plaintiffs claim these three settlements were "unlawful" because they allegedly contained "reverse payments" from Celgene to the generics. *See, e.g.*, Am. Compl. ¶¶ 4, 313-63, 406, 420. While the Amended Complaint devotes dozens of pages to recounting a wide range of events that *preceded* the settlements, when it comes time to identify the alleged "nine figure"

reverse payments therein, the Amended Complaint grows steadily vaguer and more speculative. This is unsurprising, given that there was no "nine figure" payment in any settlement.

Plaintiffs appear to argue that because, in their view—years after Celgene's patents were issued and litigated—Celgene's patents appear to Plaintiffs to be "weak," it necessarily follows that any settlement of litigation that respected a portion of those patents' terms must have been induced by a supposed "reverse payment." There is no other way to understand Plaintiffs' basis for pleading a "nine figure" payment from Celgene to each generic; their allegations offer no citation to the settlements themselves. Instead, Plaintiffs hang their scurrilous allegation that Celgene *paid* the generics *hundreds of millions* to settle the infringement suits on a comparison between: what the generics supposedly would have made had they thrown caution to the wind, and launched their generic products "at risk"[7] in November 2020, before the courts had decided whether such launches would infringe Celgene's patents; and, on the other hand, what the generics stood to earn by waiting until licensed entry dates in 2026 under the settlements. *Id.* ¶¶ 339-44. Such a circular theory would subject *every* patent settlement to the second guessing of class action counsel, and falls far short of not only well-established pleading standards but also the specific standards for pleading unlawful "reverse payments," set out in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

### A. *Actavis* Recognized Only a Narrow Exception to the General Rule That Patent Litigation Settlements Do Not Trigger Antitrust Scrutiny.

Prior to the Supreme Court's decision in *Actavis*, many courts held Hatch-Waxman settlements presumptively immune from antitrust scrutiny provided they operated within the scope

[7] "[T]he Hatch-Waxman Act . . . allows for stiff penalties for the launch of 'at risk' generic drugs—those marketed prior to the resolution of the patent litigation; an at risk launch may subject a generic manufacturer to steep infringement damages. This reflects a recognition that a valid and infringed patent maintains its lawfully granted preclusive scope." *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 752 (E.D. Pa. 2015), *aff'd*, 868 F.3d 132 (3d Cir. 2017).

of the patent's protection. *See, e.g.*, *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 208-13 (2d Cir. 2006). *Actavis* established a limited exception for settlements under which the brand made a "reverse payment" to the generic to induce settlement. But *Actavis* did not render illegal "commonplace" or "familiar" forms of settlement, including "allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration." 570 U.S. at 147-48, 152, 158. Rather, *Actavis* subjected to the antitrust rule of reason only a limited class of settlements. *Id.* at 158-59. Under *Actavis*, to proceed past 12(b)(6), Plaintiffs must identify a "settlement term at issue [that is] (1) a 'payment' that is (2) made in 'reverse'—that is, from the patent holder to the alleged infringer—and is (3) 'large,' and (4) 'unexplained.'" *In re Actos End Payor Antitrust Litig.*, 2015 WL 5610752, at *11 (S.D.N.Y. Sept. 22, 2015) (quoting *Actavis*, 570 U.S. at 158), *aff'd in part, vacated in part on other grounds*, 848 F.3d 89 (2d Cir. 2017).

The requirement to plausibly plead these specifics is not deferred to discovery; it is a threshold 12(b)(6) issue. *Id.* at *13-14 (applying "limiting principles articulated in *Actavis*"); *see also Mayor & City Council of Balt. v. AbbVie Inc.*, 42 F.4th 709, 714-16 (7th Cir. 2022) (complaint "deficient" for failure to plead cognizable payment). To take an agreement outside the zone of "legal early-entry settlement," a specific term of that settlement, not a "mere[] . . . compromise entry date," must be identified as the "reverse payment." *Actos*, 2015 WL 5610752, at *13.

An antitrust complaint must, separately, contain sufficient factual allegations for the Court to be able "to estimate the value of the [alleged payment] term," at least to the extent necessary to support a legal determination that the payment was both "large" and "unjustified." *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 552 (1st Cir. 2016) (quoting *Actos*, 2015 WL 5610752, at *13). "[B]are allegations . . . insufficient for the Court to make a reasonable estimate of the

settlements' value and determine whether they constituted large and unjustified payments" require dismissal. *Actos*, 2015 WL 5610752, at *19.

**B. Plaintiffs' Reverse Payment Theory Does Not Add Up.**

Plaintiffs bring scattershot challenges to three of nine settlement agreements with generics: those reached with the generic manufacturers Breckenridge (and its partner Natco),[8] Teva, and Aurobindo. Am. Compl. ¶¶ 345, 352, 363. In Plaintiffs' view, these agreements were not "*bona fide*, arms-length resolution[s] of the merits of the pomalidomide litigation," and the agreed-upon entry terms "do not reflect" what Plaintiffs deem to be "the patent merits." *Id.* ¶¶ 316, 356. To be sure, Plaintiffs do not allege that Celgene paid the generics cash. Instead, Plaintiffs allege, the agreements contained reverse payments by helping the three generics "protect[]" the 180 days of statutory exclusivity that they were allegedly at "risk" of forfeiting, *id.* ¶¶ 32, 323, 359; "protect[ing]" separate settlements of other litigation on a different Celgene product, Revlimid, *id.* ¶¶ 316, 324-26, 356; and [redacted] Plaintiffs also gesture at the fact that the settlements were confidential. *Id.* ¶¶ 331, 352, 363. None of these are reverse payments under *Actavis*.

* * *

The shortcomings of Plaintiffs' payment theories are explained in detail below, but two threshold issues each independently warrant dismissal.

*First*, a key characteristic of a reverse payment claim under *Actavis* is: "The patentee *and the [generic] challenger gain*" from the terms of the settlement. 570 U.S. at 154 (emphasis added). But here, Plaintiffs plead, the generic challengers were *worse off* under the terms of the settlements.

[8] Plaintiffs refer to a single settlement with "Natco/Breckenridge." Breckenridge was the company that filed the ANDA and received final FDA approval. Natco was its partner. For consistency with the Amended Complaint, Celgene similarly refers to "Natco" or "Natco/Breckenridge."

They claim that Natco and Aurobindo, rather than launch their products amidst unresolved patent litigation in November 2020, instead agreed to "wait six years," and enter an "immediately, fully genericized market," thus selling *less* of their product at *lower* prices. Am. Compl. ¶¶ 342-43. In other words, Plaintiffs flip *Actavis* on its head: rather than alleging that "the challenger gain[ed]" under the terms of the settlement, they claim the generics were worse off under these settlements. If the challenged terms were conveyances of value in either direction, under Plaintiffs' theory, it would have been *from the generics to Celgene*, *i.e.*, Plaintiffs' math runs in the opposite direction of a "reverse" payment.

*Second*, Plaintiffs' claims fail because their entire theory of the value of these alleged payments amounts to *when* the generic can sell its product—that is, the licensed entry date. But it is definitively lawful for the parties to compromise on that date. *See Actavis*, 570 U.S. at 158; *Actos*, 2015 WL 5610752, at *12 ("[S]ettlements without reverse payments, *such as those that permit a generic manufacturer to enter the patentee's market prior to the patent's expiration*, remained lawful [under *Actavis*]."") (emphasis added); *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 407-08 (3d Cir. 2015) ("[T]he *Actavis* Court expressly identified early-entry licensing as a traditional form of settlement whose legality the opinion took pains not to disturb." (cleaned up)). Only terms that contain something more—*i.e.*, separate "large" and "unjustified" consideration for the generic, beyond a compromise date of early entry—survive 12(b)(6) scrutiny. *See, e.g.*, *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 243-45 (D. Conn. 2015) ("co-promotion" and "no-authorized generic" agreements); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, 2016 WL 4992690, at *15 (S.D.N.Y. Sept. 13, 2016) (alleged "anticompetitive product-hop"). Absent any such allegation here, Plaintiffs' entire theory rests on the very form of settlement that *Actavis* left undisturbed. 570 U.S. at 152.

### C. Plaintiffs' Payment Theories Are Not Plausibly Pleaded.

To dress up their approach in the language of *Actavis*, Plaintiffs' incant the same "large" and "unjustified" "payment" labels as to each of the Natco, Aurobindo, and Teva settlements. *See, e.g.*, Am. Compl. ¶¶ 314, 346, 354. But each of Plaintiffs' "payment" theories—"conferring . . . exclusivity," "protect[ing]" the terms of other settlement agreements, "tim[ing]" simultaneous early entry dates, and "keep[ing] secret" certain settlement terms, *e.g.*, *id.* ¶¶ 4, 323, 328, 329, 331—is implausible. And even if one of these theories were cognizable, Plaintiffs have not pleaded a plausible basis to value these terms as amounting to a supposed "nine figure" reverse payment under *Actavis*. *See* Section I.D, *infra*.

#### 1. 180-Day exclusivity.

Natco, Aurobindo, and Teva were three of six "first filer" generics, having all filed their ANDAs on February 8, 2017. Am. Compl. ¶¶ 290-91. Under the Hatch-Waxman Act, therefore, they were presumptively entitled to a 180-day exclusivity period to market their generics. *Id.* ¶ 32 (citing 21 U.S.C. § 355(j)(5)(B)(iv), (D)). "During that time, the FDA may not grant final approval to any other [non-first-filer] generic manufacturer's ANDA." *Id.* This 180-day exclusivity period "can be lost" if a first-filer fails to obtain tentative FDA approval of its ANDA within 30 months of filing, but, as Plaintiffs concede, "[t]he FDA will commonly defer a decision on forfeiture until it becomes necessary to decide the issue, typically when a later filer seeks final approval for its ANDA product." *Id.* ¶ 34; *see, e.g.*, *Hi-Tech Pharmacal Co. v. FDA*, 587 F. Supp. 2d 1, 5 (D.D.C. 2008) (explaining that FDA's "general practice is to decide issues of exclusivity and forfeiture only when an ANDA is ready for final approval").[9]

[9] As explained *infra*, at 14-15, as a matter of law, so long as any one of the first-filers preserved 180-day exclusivity, all six are entitled to it.

That is what the FDA did here. It "deferred a decision on the 180-day exclusivity question" as to first-filers Natco and Aurobindo, Am. Compl. ¶ 309 n.97, and then confirmed—when a later-filed ANDA was tentatively approved—that the later filer would have to await the running of that exclusivity period, *id.* ¶¶ 323, 359. As Plaintiffs made clear when they pled their original complaint, "[t]here [wa]s no forfeiture here." ECF 6 ¶ 40 n.17. Whatever Plaintiffs' cursory speculations in the *Amended* Complaint about whether Natco or Aurobindo had previously faced a "risk" of forfeiting their exclusivity, Am. Compl. ¶ 292, it is undisputed that no such forfeiture occurred.

Undeterred by that conceded reality, Plaintiffs allege Celgene provided "protection of the risks" that these two first-filers (but *not* the other four) had forfeited their 180-day statutory exclusivity by granting them so-called "contractual exclusivity." *Id.* ¶¶ 323, 359. Plaintiffs' theory is that, for some period, the Natco and Aurobindo settlements provided an undefined, unquantified "protection" against "risks" that these two generics might hypothetically forfeit their statutory exclusivity.

Plaintiffs' speculation is not a plausible pleading of a "reverse payment." As an initial matter, what Plaintiffs term a "contractual exclusivity" provision simply accelerates earlier in time the patent license for a generic to launch its product. [redacted] Accelerating the patent license is not unlawful. *Actos*, 2015 WL 5610752, at *15; *see also* Section I.C.3, *infra*. Antitrust law does not somehow impose on Celgene an obligation to *delay* the effective date of a patent license. Accelerating the patent license enables the generic to sell its product earlier to the benefit of competition; it cannot itself be a "reverse payment." *Actos*, 2015 WL 5610752, at *14-16, *20.

Plaintiffs' "exclusivity" allegations fail for additional, independent reasons. *First*, Plaintiffs plead that Natco—as of the time of the challenged settlements—*would have expected to preserve*, and profit off of, its first-filer exclusivity. Specifically, far from pleading that Natco faced some risk of forfeiture, in purporting to tally the revenue such a generic would have expected to generate, Plaintiffs plead that Natco *would have expected to profit from the exclusivity*. Am. Compl. ¶ 339 ("If the only ANDA generic to enter the market was Natco[], a single first filer with 180 days of exclusivity would expect to take roughly half of these generic sales."). This is not pleading in the alternative, nor is it some offhand remark in the Amended Complaint—it is the entire premise of Plaintiffs' theory of a purported "nine figure" pay-off theory. *Id.* ¶¶ 338-41. Plaintiffs thus rely on *preserved* (not *forfeited*) exclusivity for their allegation of what a "reasonable company in the position of Natco[] . . . would expect" to earn as "one of only two finally approved ANDA applicants" in "November 2020," *id.* ¶ 341—that is, the month in which Natco settled with Celgene, a year before the FDA made its final exclusivity determination, *id.* ¶¶ 314 (settlement in November 2020), 323 (FDA subsequently confirming the exclusivity). Plaintiffs have pled themselves out of a theory that it was the settlements that "protected" Natco or Aurobindo's exclusivity—they plead just the opposite, *i.e.*, that before and notwithstanding those settlements, they would expect exclusivity.

*Second*, as Plaintiffs concede, the FDA "commonly" defers decisions on forfeiture. *Id.* ¶ 34. The predicate of Plaintiffs' theory, therefore, is that there is *always* a "risk" that a first-filer will fail to retain its statutory exclusivity, up until the moment the FDA makes an official statement to the contrary. Merely adverting to such a vague, ever-present, and unquantifiable risk cannot suffice under *Actavis* or *Twombly*. As the court explained in *Actos*, "a reading of *Actavis* that would compel antitrust scrutiny of a settlement regardless of whether its terms could reasonably

be construed as a large and unjustified reverse payment would ignore the limiting principles set forth in the decision, and subject virtually *any* settlement to antitrust scrutiny—a result the Court could not have intended." 2015 WL 5610752, at *14. Indeed, Plaintiffs plead no facts whatsoever to plausibly suggest that any risk facing either Natco or Aurobindo was unusual in any respect; they observe only that their pomalidomide ANDAs had not received "tentative" approval within 30 months of filing, but concede that that in itself does not forfeit exclusivity. Am. Compl. ¶¶ 34, 291. As noted, Plaintiffs also concede that it did not lead to forfeiture for either of these two ANDAs. *Id.* ¶¶ 323, 359. Ultimately, Plaintiffs recognize a burden to plead that any risk to the first-filers was "significant," but all they do is plead that *conclusion*, with zero facts to support it. *See id.* ¶ 292.

*Third*, Plaintiffs claim that Celgene provided "protection" against a "risk" of forfeiture of 180-day exclusivity for only two (Natco and Aurobindo) of the six first-filer generics. *Id.* ¶¶ 316, 356. Even had Plaintiffs plausibly pled that any such "protection" somehow constituted a payment to those *two* generics, they say nothing about the other four. But the rule is that so long as any *one* of multiple first-filers preserves its exclusivity, *all of them are permitted to participate in it*. *See* FDA, Guidance for Industry: 180-Day Exclusivity 26 (Jan. 2017);[10] *see also Actavis*, 570 U.S. at 174-75 (Roberts, C.J., dissenting) (citing FDA, Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day 4 (July 2003)); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, 2018 WL 7197233, at *6 (S.D.N.Y. Dec. 26, 2018) ("[M]ultiple filers may share the exclusivity period if they file on the same day."). In other words, the exclusivity operates as a bar against later filers, *not* other first-filers; thus, even if Natco and

[10] "[A] first applicant that has forfeited exclusivity remains a first applicant and need not await expiration of 180-day exclusivity to obtain approval of its ANDA." *Available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-180-day-exclusivity-questions-and-answers.

Aurobindo had (counterfactually) actually forfeited their statutory 180-day exclusivity, that would not have precluded them from enjoying the exclusivity extended to the other four first-filers. And whatever "risk" of forfeiture Plaintiffs say Natco and Aurobindo faced, Plaintiffs do not even attempt that bare pleading *as to the other four first-filers*. The upshot is that Plaintiffs have not pleaded that Natco or Aurobindo faced even a "risk" of losing out on the 180-day exclusivity period, and their settlements therefore could not be said to have unlawfully protected against that non-existent risk.

Plaintiffs' "exclusivity" theory is a house of cards: it fails on the law; it is founded on speculation contradicted by Plaintiffs' own allegations; and it pleads facts *undermining* any notion that the settlements with Natco and Aurobindo gave those two generics any "reverse payment."

**2. "Protecting" unrelated settlements on Revlimid.**

Plaintiffs devote pages of allegations to separate settlements regarding different patents on a different medicine manufactured by Celgene: Revlimid. *See, e.g.*, Am. Compl. ¶¶ 325-29, 337, 349, 356, 360. They allege that the Pomalyst settlements were somehow "designed to protect" the Revlimid settlements, *id.* ¶ 328, but they do not plead how the Pomalyst settlements would do so. None of the three Pomalyst settlements even references Revlimid, and *Plaintiffs do not cite any provision of the Pomalyst settlements that would somehow "protect" Revlimid*.

*First*, even had Plaintiffs identified any basis for this theory, it would be nonsensical: how would "protection" of settlements on *Revlimid* somehow constitute a "reverse payment" to delay generic entry on *Pomalyst*? Plaintiffs purport to seek recovery only in connection with purchases of Pomalyst, not Revlimid. *Id.* ¶¶ 374, 376. These are wholly separate products; indeed, Plaintiffs affirmatively allege that their "relevant market" consists exclusively of "Pomalyst and its AB-rated generic equivalents," and that "no other products" (including Revlimid) are therapeutic substitutes for Pomalyst. *Id.* ¶¶ 388, 393. What would the "reverse payment" in the Pomalyst settlements

even be in the (counterfactual) scenario Plaintiffs envision? This is more than a question of plausibility under *Twombly*; there is no articulation whatsoever of the "payment" aspect of the illusory connection Plaintiffs allege.

*Second*, and in any event, Plaintiffs' allegations that the *Revlimid* settlements are unlawful because they license limited volumes of generic Revlimid under Celgene's Revlimid patents have nothing whatsoever to do with this case. Those allegations are the subject of antitrust complaints in New Jersey, where motions to dismiss are pending. *In re Revlimid & Thalomid Purchaser Antitrust Litig.*, No. 19-cv-7532-ES-MAH (D.N.J.). Plaintiffs (represented by the same counsel), who are purportedly absent members of a putative class there, cannot bootstrap the existence of *those* claims into a basis to proceed *here*. Such bootstrapping would not work even if, instead of Plaintiffs, some government agency had made such a claim on Revlimid in New Jersey (none has). *See In re Elevator Antitrust Litig.*, 502 F.3d 47, 51-52 (2d Cir. 2007) (investigations into conduct in one context failed to plausibly suggest anticompetitive conduct in a different context, amounting to nothing more than "if it happened there, it could have happened here").

**3. "Simultaneously timed" early entry dates.**

In Plaintiffs' telling, settlements that result in "simultaneously timed" early entry dates somehow reflect a reverse payment. Am. Compl. ¶ 4. Plaintiffs do not explain why such a provision should be deemed a payment at all, much less one that is large and unjustified. That is unsurprising: *Actos* squarely rejected the same theory under a different name.

In *Actos*, the plaintiffs alleged that settlements between a brand and a generic contained unlawful reverse payments in the form of "acceleration clauses," which provided that, if any other generic entered the market before a certain early entry date, the generic counterparties to the settlement agreements would also be able to enter on that same earlier date. 2015 WL 5610752, at *6. Here, though Plaintiffs do not cite any specific settlement provisions, their allegations of

[redacted]

Celgene negotiated separate settlements with each of Natco, Teva, and Aurobindo. The Natco settlement, reached in November 2020, licensed Natco to Celgene's patents [redacted] Teva settled in March 2021, negotiating a license [redacted] And Aurobindo settled in July 2021 for a license [redacted]

*Actos* found it "difficult to view the [acceleration] provisions as 'payments'" at all because the generic defendants would be receiving value not from the patentee, but rather, through the market, if and when the generics began selling the product. 2015 WL 5610752, at *15. Moreover, as *Actos* explained, the "practical effect" of such provisions was only "to increase competition in the event that other generics entered the market earlier than contemplated by the agreement." *Id.* In other words, the triggering of an acceleration clause had "an indisputably procompetitive effect," and the acceleration clauses only affected the entry date—a date that could lawfully be agreed upon by the settling parties under *Actavis*. *Id.* at *15-16. So too here. Accelerating the

licensed entry dates earlier in time yields more generic competition earlier in time, *i.e.*, *increased* competition. Plaintiffs fail to plead how simultaneous entry by two (or more) generics amounts to a "reverse payment" of any kind.

**4. Confidentiality.**

Plaintiffs allege that "the facts surrounding the non-disclosure of the settlement *show* that the . . . agreement contains an anticompetitive reverse payment." Am. Compl. ¶ 330 (emphasis added); *see also id.* ¶¶ 331, 335. How it is that confidentiality—a linchpin of most litigation settlements—somehow "shows" a "reverse payment" is nowhere pleaded. And, to be sure, the assertion of "absolute secrecy," *id.* ¶ 4, in these settlements (even were that plausibly indicative of anything) is false as a matter of law: the settlements were all required by law to be submitted to the DOJ and FTC, *see* Pub. L. No. 108-173, tit. XI, subtit. B, 117 Stat. 2461, notes on 21 U.S.C. § 355. Plaintiffs themselves reviewed two[11] settlements before amending their complaint. Plaintiffs' confidentiality allegations do not plead a "reverse payment" either.

**D. None of Plaintiffs' Payment Theories Pleads a Plausible Link Between the Alleged Payments and the Alleged Value of Those Payments.**

Not only do Plaintiffs fail to plead a plausible payment cognizable under *Actavis*, but they also fail to plead that any such payment was "large" and "unjustified," which would require them to "plausibly allege a factual basis for the Court to reasonably estimate the value of the settlement terms." *Actos*, 2015 WL 5610752, at *19. For all of its 600+ paragraphs, the Amended Complaint does not *connect* any of Plaintiffs' payment theories to their calculation of a "nine figure" pay-off

[11] Teva, the counterparty to the third challenged settlement, initially objected to producing its settlement to Plaintiffs after Plaintiffs dismissed all of their claims against Teva. ECF 42. It is publicly known that Teva, which agreed to a consent order with the FTC in 2019, submits its patent settlements to the FTC before signature; that is presumably why Plaintiffs dismissed Teva as a defendant in this case. When Plaintiffs nevertheless continued to pursue claims against Celgene related to the Teva settlement, Teva consented to the settlement being attached to this motion to dismiss.

(Am. Compl. ¶ 338); Plaintiffs could hardly plead such a connection, for those nine figure sums are calculated as value that Natco allegedly *lost*, not value that Natco *gained*. *See* Section I.B, *supra*.

Three independent bases for dismissal thus become apparent on the face of Plaintiffs' reverse payment claims. *First*, Plaintiffs fail to plead the value of any of the challenged provisions. Instead, all that Plaintiffs do—and only with respect to one of the three challenged settlements, with Natco—is some back-of-the-envelope math on how much Natco stood to earn had it launched its generic product in November 2020, more than a decade before patent expiry, amidst the patent litigation and without judicial resolution over whether such sales would infringe any of the patents. Am. Compl. ¶ 341. That is, Plaintiffs' basis for the hyperbolic claim that Celgene "paid off" Natco with a sum in the "nine figures" is to tally what Natco could have made had it chosen to launch "at risk" of patent infringement, rather than reach a settlement with a license commencing several years later. If to plead a reverse payment claim it were sufficient simply to plead that Natco stood to make less by compromising the patent infringement litigation than by launching at risk, then *every single patent settlement* would inherently contain a "large" and "unjustified" reverse payment in the amount of the profits that the generic had forgone in compromise. No court has ever endorsed such a limitless and backward conception of *Actavis*, under which any non-party to the settled patent litigation (such as Plaintiffs here) could come along years later, proclaim its opinion that the patents were worthless, insist that rather than compromise there must have been a "pay-off," and seek treble damages.

*Second*, Plaintiffs fail to plead an actual *link* between any of the provisions they challenge and their conclusion of a "nine figure" reverse payment. That is, apart from the legal insufficiency of their challenges to each of those provisions (Section I.C, *supra*), Plaintiffs do not plead any

connection between those provisions and the gargantuan figure they claim the generics were "paid off" with. Put another way, even had Plaintiffs alleged a plausible theory of payment (which they have not), the absence of any alleged connection between such a payment and the "large" and "unjustified" labels would independently be fatal to the Amended Complaint's reverse payment claims. *See Actos*, 2015 WL 5610752, at *19 (rejecting as insufficient plaintiffs' allegations that licensing terms in settlement agreements were "of substantial value and worth . . . hundreds of millions of dollars" because "*Twombly* requires more than mere 'labels and conclusions' to state a claim for relief" (quoting *Twombly*, 550 U.S. at 555) (cleaned up)); *see also City of Pontiac Police & Fire Ret. Sys.*, 92 F.4th at 415 (affirming dismissal of antitrust conspiracy claims where complaint relied on "terminology" rather than any agreement, used "labels . . . without substance," and described conduct that was "as easily indicative" of lawful purpose as any unlawful one).

*Third*, even if Plaintiffs' theory that "the settlements must have been worth nine figures" worked as to Natco (it does not), Plaintiffs do not even attempt that circular mathematical exercise for either of the two other settlements (with Teva and Aurobindo) that Plaintiffs purport to challenge. Am. Compl. ¶ 352 (no attempted articulation of an alleged payment to Teva); *id.* ¶ 363 (same omission as to Aurobindo). Plaintiffs' abrupt decision in late 2023 to dismiss their claims against *all* of these generics, *see* ECF 42 (Teva), 73 (Aurobindo), 74 (Natco/Breckenridge), 75 (Natco), should not obfuscate these obvious gaps in the Amended Complaint; Plaintiffs have no valid reverse payment challenge to any of the three settlements.

## II. PLAINTIFFS FAIL TO PLEAD COGNIZABLE CHALLENGES TO CELGENE'S PATENTS AND PATENT LITIGATIONS.

Plaintiffs challenge not only Celgene's settlements with the generic manufacturers, but also the mere fact that Celgene initiated patent litigation to protect its intellectual property at all. As a matter of law, patentees in general, and those operating under the Hatch-Waxman framework in

particular, have wide latitude to enforce their patent rights through litigation. "[B]y virtue of the right to petition guaranteed by the First Amendment, attempts to influence . . . judicial action are immune from federal antitrust liability," a doctrine known as *Noerr-Pennington* immunity. *Twin City Bakery Workers & Welfare Fund v. Astra Aktiebolag*, 207 F. Supp. 2d 221, 223 (S.D.N.Y. 2002) (describing the doctrine); *see also In re Actos End-Payor Antitrust Litig.*, 417 F. Supp. 3d 352, 374 (S.D.N.Y. 2019) ("[a] patentee who seeks to enforce its patent through litigation" generally enjoys *Noerr-Pennington* immunity).

Plaintiffs here try to strip Celgene of its *Noerr-Pennington* antitrust immunity. They allege that six of Celgene's nine pomalidomide patents were acquired by so-called *Walker Process* fraud on the PTO, and then argue that Celgene's commencement of patent litigation against every one of the nine generics was a "sham." Plaintiffs fail to sufficiently plead around Celgene's immunity, and their claims should be dismissed.

### A. As Indirect Purchasers, Plaintiffs Lack Antitrust Standing to Pursue *Walker Process* Fraud Claims.

Plaintiffs' *Walker Process* claims fail at the threshold because they lack standing to bring them. As courts have held, "*Walker Process* does not confer standing on a party whose only connection to the patentee is as an indirect purchaser of products covered by the patent." *E.g.*, *Farag v. Health Care Serv. Corp.*, 2017 WL 2868999, at *4-6 (N.D. Ill. July 5, 2017). Allowing Plaintiffs, an insurer and a consumer, to proceed here would invite other indirect purchasers to inundate the very circuit that has sought to "tread carefully" in this area, lest it unduly "expand[] the universe of patent challengers" and risk "disturbing incentives for innovation." *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 691 (2d Cir. 2009). Indeed, if Plaintiffs had standing, then any one of potentially thousands of third-party payors that provides indirect reimbursement for a medicine would be permitted, years after patent issuance and in spite of the

public records of patent prosecutions, to stand by and watch as those patents are prosecuted, narrowed, and then issued at the PTO; watch as those patents are litigated and resolved by settlement; embark some ten to twenty years post-prosecution on their own independent review of the patents; and claim, for the first time, that the patents were obtained by fraud and should never have been enforced, entitling these downstream actors to treble damages. This runs contrary to well-established antitrust law.

Antitrust standing is a "threshold, pleading-stage" matter. *In re Am. Express Anti-Steering Rules Antitrust Litig.*, 19 F.4th 127, 138 (2d Cir. 2021) (cleaned up). Plaintiffs must demonstrate not only that they have suffered antitrust injury but also that they are proper antitrust plaintiffs under several factors:

> (1) the directness or indirectness of the asserted injury; (2) the existence of an identifiable class of persons whose self-interest would normally motivate them to vindicate the public interest in antitrust enforcement; (3) the speculativeness of the alleged injury; and (4) the difficulty of identifying damages and apportioning them among direct and indirect victims so as to avoid duplicative recoveries.

*In re DDAVP*, 585 F.3d at 688. These factors counsel against standing for these plaintiffs to bring their *Walker Process* claims here. *First*, as indirect purchasers, Plaintiffs allege antitrust injury several steps removed from the years-old PTO and litigation conduct they challenge. All Plaintiffs allege is that they either paid pharmacies, or reimbursed unspecified entities who had previously paid pharmacies, which in turn had purchased Pomalyst from Celgene. By definition, such derivative injuries are too remote to satisfy the "first-step rule," grounded in principles of proximate cause, that the Second Circuit has "repeatedly followed . . . in the antitrust context." *In re Am. Express*, 19 F.4th at 139-41. *Second*, alternative "enforcers"—like the generic competitors that Celgene sued for infringement—are better situated than Plaintiffs to challenge the validity of Celgene's patents, such that no alleged antitrust violation would go unremedied. *Id.* *Third*, Plaintiffs' theory of indirect injury—under which they reimbursed unspecified entities who in turn

paid pharmacies for Pomalyst, which pharmacies had purchased the product from Celgene—necessarily involves intermediaries and intervening factors, creating an "accompanying uncertainty," *id.* at 142, and "requir[ing] the court to speculate" about how each intermediary would have behaved had none of the patents issued, *see Schwab Short-Term Bond Mkt. Fund v. Lloyds Banking Grp. PLC*, 22 F.4th 103, 119 (2d Cir. 2021). *Fourth*, the requested relief, "even if in the form of an injunction . . . compounds manageability issues without providing any clear benefit," particularly where there are better-situated alternative enforcers. *In re Aluminum Warehousing Antitrust Litig.*, 2014 WL 4277510, at *23 (S.D.N.Y. Aug. 29, 2014). Finally, when patents are involved, courts must consider how their standing analysis will affect "incentives for innovation." *In re DDAVP*, 585 F.3d at 691; *see also, e.g.*, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 542 (E.D.N.Y. 2005) (weighing whether more expansive standing would "negatively impact the willingness of drug manufacturers to invest in research and development").

None of the Plaintiffs here alleges to have ever purchased Pomalyst (or anything else) directly from Celgene. *See* Am. Compl. ¶ 476 ("[P]laintiffs and Class members . . . indirectly purchased Pomalyst."). In the *Walker Process* context in particular, courts have recognized that such plaintiffs pose unique policy concerns, and dismissed indirect-purchaser claims for lack of antitrust standing. *See, e.g.*, *Farag*, 2017 WL 2868999, at *4-6; *In re K-Dur Antitrust Litig.*, 2007 WL 5297755, at *17-19 (D.N.J. Mar. 1, 2007) ("If this Court were to conclude that *indirect* purchasers had standing to bring *Walker Process* claims, it would turn antitrust policy on its head, and extend antitrust standing to an extraordinary level[.] . . . [A]s compared to competitors and direct purchasers, indirect purchasers have certainly been *less* 'directly harmed.'"). Broader antitrust policy considerations support their holdings. *See Associated Gen. Contractors of Cal.,*

*Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 542 (1983) (reasoning that the "existence of an identifiable class of persons whose self-interest would normally motivate them to vindicate the public interest in antitrust enforcement diminishes the justification for allowing a more remote party" to bring such a suit); *see also Kaiser Found. v. Abbott Lab'ys*, 2009 WL 3877513, at *3-5 (C.D. Cal. Oct. 8, 2009) ("[T]he fundamental reason consumers have been found to lack antitrust standing to bring a *Walker Process* claim in the Hatch-Waxman context is because Congress has failed to legislatively grant them that standing."). The generics in the patent litigations indisputably had such standing, and Plaintiffs concede that not one of them claimed any such fraudulent scheme as to the patents they were accused of infringing.

*In re DDAVP* further supports dismissal for lack of standing. There, the Court of Appeals, addressing antitrust claims brought by direct purchasers regarding a patent that had previously been held (in litigation with generics) to have been procured by fraud, expressed reservations about "expanding the universe of patent challengers" even to those *direct* purchasers, given the risk such an expansion would pose to "incentives for innovation." 585 F.3d at 691. Accordingly, it reasoned that it would "tread carefully" in reaching its narrow holding: "*only* that [the direct] purchaser plaintiffs have standing to raise *Walker Process* claims for patents that *are already unenforceable due to inequitable conduct*." *Id.* at 691-92 (emphases added). *In re DDAVP*'s concerns about permitting a *Walker Process* claim absent an "already tarnished patent" (of which there are none here), *id.* at 691, and the further remoteness of the *indirect* purchaser Plaintiffs in this case, militate squarely against antitrust standing here.

Consistent with Circuit precedent and broader antitrust policy considerations, this Court should dismiss Plaintiffs' *Walker Process* claims for lack of antitrust standing.

**B. Plaintiffs Fail to Plausibly Plead *Walker Process* Fraud.**

Even if Plaintiffs had standing, their patent-related claims fail to state a claim in any event. Their theory is as sweeping as it is fantastical: that each of six Orange Book-listed pomalidomide patent Celgene held was acquired via fraud on the PTO, and so Celgene's patent suits asserting them entitle Plaintiffs to treble damages under the antitrust laws. Although *each generic* had access to the *same materials* Plaintiffs now cite, *not a single one* pleaded that Celgene engaged in fraud or inequitable conduct with respect to any pomalidomide patent. Plaintiffs now claim to know better.

A claim for *Walker Process* fraud requires: (1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, (4) but for which misrepresentation or deliberate omission the patent claims would not have issued. *In re DDAVP*, 585 F.3d at 692 (citation omitted). In the last decade, courts have "tightened" the standards for pleading such claims precisely because the claims had become "overplayed," and an "absolute plague" that was "cluttering up the patent system." *Kowa Co. v. Sawai USA, Inc.*, 2016 WL 3681459, at *3 & n.2 (S.D.N.Y. July 5, 2016) (cleaned up).

As with any claim grounded in fraud, Plaintiffs also must satisfy Rule 9(b)'s demanding pleading standard. *Radiancy, Inc. v. Viatek Consumer Prods. Grp., Inc.*, 138 F. Supp. 3d 303, 324 (S.D.N.Y. 2014). That is, Plaintiffs must identify "the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009). As to each statement or omission, Plaintiffs must "identify which claims [of the patent], and which limitations in those claims," are impacted by an alleged misrepresentation. *Id.* at 1329. Plaintiffs must also "plead with particularity the materiality of [any] references [that] the patent applicant omitted," including by

explaining how "but for" the omissions, the PTO would not have granted the patent. *Radiancy, Inc.*, 138 F. Supp. 3d at 324. And with respect to intent, Plaintiffs must plead "facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." *Exergen*, 575 F.3d at 1328-29.

Plaintiffs do not come close to satisfying this demanding standard for any of the six patents they claim were procured by fraud. Instead, their allegations "appear to be little more than an ineffective attempt to dress up a garden-variety invalidity [theory]." *Lakim Indus., Inc. v. Linzer Prods. Corp.*, 2012 WL 12547988, at *5 (C.D. Cal. Nov. 7, 2012). But dress it up well, Plaintiffs do not. Instead, over and over, the Amended Complaint mischaracterizes or simply omits the actual text of the public documents it relies on.[12] Plaintiffs ignore that Celgene repeatedly *gave* the patent examiners the same source material that Plaintiffs complain was misrepresented or omitted. And Plaintiffs never allege with particularity how any purported misstatement or omission was *but-for material*, such that the patent examiner would not have issued a particular patent claim but for the alleged misrepresentation or omission. The law is clear that such allegations do not state a claim for *any* wrongdoing, let alone for fraud.

**1. Plaintiffs fail to plausibly allege that Celgene's method-of-treatment patents were acquired by fraud.**

Plaintiffs attack three patents related to methods of treatment: the '262, '428, and '3939. Celgene filed the first of these patent applications in 2008; they issued between 2012 and 2014;

[12] Because the relevant patent prosecution documents are both publicly available and relied upon by the Amended Complaint, they are properly the subject of judicial notice and may be considered as part of a motion to dismiss. *See Telebrands Corp. v. Del Lab'ys, Inc.*, 719 F. Supp. 2d 283, 287 n.3 (S.D.N.Y. 2010) ("The Court may properly take judicial notice of official records of the [PTO]."); *In re Buspirone Pat. Litig.*, 185 F. Supp. 2d 363, 367 (S.D.N.Y. 2002) ("In deciding the motion [to dismiss], the Court may consider documents referenced in the Complaint[] and documents that are in the relevant antitrust plaintiffs' possession or that they knew of and relied on in bringing suit.").

and the last of them expires in 2025. Am. Compl. ¶ 152. Plaintiffs' various claims of purported fraud in the issuance of these patents fail to state a claim as a matter of law.

***a. The D'Amato patents.***

Plaintiffs' pre-motion letter made much of the allegation that, *in 2002*, Celgene bought and "bur[ied]" one pomalidomide patent and four patent applications from Dr. Robert D'Amato and his development partner EntreMed (together, the "D'Amato patents"). ECF 98, at 2. The Amended Complaint does not tie this fact to any particular *Walker Process* claim, but broadly alleges that the purchased patents and applications disclosed the use of pomalidomide to treat "undesired angiogenesis," and implies that Celgene was attempting to keep this information from the PTO while prosecuting its method-of-treatment patents. Am. Compl. ¶¶ 154-59, 183-84. That Celgene acquired these rights states no claim whatsoever, much less for fraud.

*First*, the breezy allegation that Celgene "buried" the D'Amato patents in seeking its own is false on the face of the documents incorporated into the 12(b)(6) record: Celgene *cited to the examiner* at least fifteen of Dr. D'Amato's patents and patent applications in connection with *each* method-of-treatment patent. *E.g.*, Ex. D, at 46-47. Indeed, the work of Dr. D'Amato in this area was disclosed in the initial '262 patent application itself *in August 2008*, as reflected here:

> Other diseases or conditions associated with, or characterized by, undesired angiogenesis are also difficult to treat. However, some compounds such as protamine, hepain and steroids have been proposed to be useful in the treatment of certain specific diseases. Taylor et al., *Nature* 297:307 (1982); Folkman et al., *Science* 221:719 (1983); and
> 25 U.S. Pat. Nos. 5,001,116 and 4,994,443. Thalidomide and certain derivatives of it have also been proposed for the treatment of such diseases and conditions. U.S. patent nos. 5,593,990, 5,629,327, 5,712,291, 6,071,948 and 6,114,355 to D'Amato.

Ex. D, at 35. Included among the D'Amato patents cited to the PTO are (i) two of the *very applications* that Plaintiffs claim were "buried"; (ii) the application for the *very patent* that

Plaintiffs claim was "buried"; and (iii) patents in the identical "patent family"—that is, patents that share a common specification and contain nearly identical disclosures—as the remaining two applications that Plaintiffs claim were "buried." Plaintiffs do not (and cannot) allege how those two particular applications are not cumulative of the *three* D'Amato patents cited from *the same patent family*. *See* Appendix 1, *infra*.[13] That is, all five of the supposedly "buried" sets of disclosures were actually disclosed. Nothing was "buried," and there is no plausible pleading of any "fraud."

These undisputed facts are evident on the face of the prosecution history record, and Celgene obviously "[cannot] be guilty of inequitable conduct if the reference was cited to the examiner." *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1327 (Fed Cir. 2000). That Plaintiffs unearthed none of these disclosures, even in amending their complaint, is reflective of their singular focus on salacious adjectives rather than plausible allegations.

*Second*, Plaintiffs do not allege how the acquired D'Amato patents were material to any specific patent claim (or even a *specific patent at all*) at issue here. *See Exergen*, 575 F.3d at 1329. Nor do they allege how the D'Amato patents were not cumulative of all of the sources Celgene cited to the examiner. *See id.* at 1329-30 (plaintiffs must allege "'why' the withheld information is material and not cumulative, and 'how' an examiner would have used this information in assessing the patentability of the claims"); *see also Rothman v. Target Corp.*, 556 F.3d 1310, 1326 (Fed. Cir. 2009) ("A piece of prior art is not material to patent prosecution when it is cumulative

[13] Patent applications are assigned *two* identification numbers: a patent application serial number (consisting of a two-digit series code followed by a six-digit serial number, like 10/166,539), *and*, once the application is published, a publication number (consisting of a year, followed by a seven-digit sequence code and a two-character kind code, like 2002/0161023 A1). *See* PTO, *Search for Application*, https://www.uspto.gov/patents/search/search-application (explaining the different numbering systems). This may explain Plaintiffs' failure to identify applications, like the one they identify as 09/899,344, that were disclosed to the examiner by publication number (in that case, as the 2001/0056114).

of information already before the examiner."). Plaintiffs have thus failed to meet their pleading burden as a matter of law with respect to the D'Amato patents.

***b. The '262 method-of-treatment patent.***

*1) Plaintiffs allege no material misstatement or omission.*

The '262 patent claims the use of pomalidomide in combination with dexamethasone to treat multiple myeloma using specific doses and schedules. Am. Compl. ¶ 163. Plaintiffs focus on two submissions from Celgene to the examiner—in December 2010 and December 2011—in response to the examiner's interim rejection of certain proposed claims. *Id.* ¶¶ 165, 167, 184, 186. As to the December 2010 submission, Plaintiffs allege that Celgene failed to correct the examiner's supposed misunderstanding of two scientific references, and failed to bring a third reference back to the examiner's attention. *Id.* ¶¶ 168, 175-76. As to the December 2011 submission, Plaintiffs allege that Celgene misrepresented information that was purportedly reflected in the literature about the use of pomalidomide to treat multiple myeloma. *Id.* ¶¶ 187-89. Finally, Plaintiffs point to the examiner's summary of a March 2012 phone call between Celgene and the examiner, alleging that someone said *something* false or misleading during that discussion, but without any further detail. *Id.* ¶ 191.

Plaintiffs' allegations as to each of these three exchanges fails on the face of their pleading for the same reason: they do not identify a *material misstatement or omission* any individual made, much less with the level of particularity required by Rule 9(b). In addition, Plaintiffs' allegations as to Celgene's December 2010 and December 2011 submissions fail for the independent reason that, as Plaintiffs acknowledge, Celgene *subsequently amended* its proposed patent claims to address the examiner's concerns. *See id.* ¶ 193. Plaintiffs do not even bother to try and explain how, as a matter of law, Celgene's responses to earlier-in-time rejections addressing outdated claims could *possibly* be material to the patentability of the claims that ultimately issued.

*2) The prosecution record contradicts Plaintiffs' allegations.*

a) Celgene's December 2010 Submission.

None of Plaintiffs' allegations about the three references that they claim were mischaracterized or withheld from this submission states any claim for fraud.

***The '517 Patent Reference.*** Plaintiffs allege Celgene misrepresented information about the '517 reference, which the examiner in June 2010 appeared to have raised as a basis for rejecting Celgene's then-pending claims for what would become the '262 Patent. Celgene had affirmatively disclosed the '517 reference to the examiner in its *initial application* in 2008, *see* Ex. D, at 40, 43, 47, well before these alleged misrepresentations. Plaintiffs focus on only one sentence from page 7 of Celgene's December 2010 submission, which Plaintiffs characterize as stating that the '517 reference did not "teach ACTIMID." Am. Compl. ¶ 174. Plaintiffs allege that, in fact, "the '517 patent did teach pomalidomide," which they characterize as synonymous with ACTIMID. *Id.*

Once again, Plaintiffs' hyperbole—they cite this allegation to baldly assert that Celgene's counsel "lied," ECF 100, at 3—led them to skip over the face of the record they incorporate into their Amended Complaint. That record is irreconcilable as a matter of law with any allegation of a misrepresentation, much less a material one that the examiner actually relied on.

*First*, Plaintiffs fail to plausibly allege that Celgene's statements to the examiner about the '517 reference were even false. Plaintiffs allege that the false statement was Celgene's purported confirmation of the examiner's view that the '517 reference did not "teach ACTIMID." Am. Compl. ¶ 174. But as reflected in the record, Celgene accurately explained to the examiner exactly how the '517 reference's disclosures differed from the then-pending claims it was seeking to patent—that is, what Celgene actually argued was that the '517 did not teach treating *a specific disease with certain specific methods*:

> The claimed invention relates, *inter alia*, to specific methods of treating multiple myeloma by administering specific amounts (about 0.5 to 4 mg/day) of a specific compound known as 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione (pomalidomide or Actimid®). The claimed invention also relates to very specific combination therapy with dexamethasone and cyclic dosing regimen.
>
> The primary reference fails to suggest the treatment of multiple myeloma within these claimed methods. The PTO admits that the primary reference does not teach ACTIMID (page 5 of the Action). Thus, the primary reference does not direct the skilled person to use the recited compound in the treatment of multiple myeloma.

Ex. D, at 79. Plaintiffs do not allege (nor could they) that the '517 reference *actually taught* the use of pomalidomide in combination with dexamethasone to treat multiple myeloma, *i.e.*, the invention in the claims of the '262 that ultimately issued. Rather, because the examiner "had the ['517] [r]eference to refer to" and "was free to reach his own conclusions and accept or reject [Celgene's] arguments," Celgene's "interpretation of what the ['517 reference] disclose[d]" and how it differed from the proposed claims of the '262, cannot, as a matter of law, "constitute affirmative misrepresentations of material fact." *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007). "As the Federal Circuit has recognized, the mere fact that a patent applicant attempts to distinguish its patent from the prior art does not constitute a material omission or misrepresentation where the patent examiner has the prior art before him or her, and therefore, is free to make his or her own conclusions regarding the claimed invention." *LifeScan, Inc. v. Home Diagnostics, Inc.*, 103 F. Supp. 2d 379, 386 (D. Del. 2000), *aff'd*, 13 F. App'x 940 (Fed. Cir. 2001).

*Second*, Celgene made clear for the examiner in its initial application in August 2008 that the '517 reference taught one skilled in the art how to make the pomalidomide compound:

> The most preferred immunomodulatory compounds of the invention are 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione and 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione. The compounds can be obtained via standard, synthetic methods (*see e.g.*, United States Patent No. 5,635,517, incorporated herein by reference). The compounds are available from Celgene Corporation, Warren, NJ. 4-(Amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione (ACTIMID™) has the following chemical structure:

Ex. D, at 43.[14] In other words, Celgene's August 2008 submission made clear exactly what Plaintiffs claim was misrepresented in December 2010; Celgene's later correspondence did not somehow cause its prior statement to magically disappear. There is no pleaded basis for Plaintiffs' conclusion that the examiner failed to recognize the relevance of the '517 reference, nor for Plaintiffs' conclusion of any intent by Celgene to hide *what it had expressly disclosed* in its description of its invention. Certainly, Plaintiffs cannot avoid reality by simply ignoring the language from the prosecution record and the issued patent that they challenge, both of which are incorporated by reference into the Amended Complaint. Am. Compl. ¶¶ 159, 168.

*Third*, nothing Celgene told the examiner with respect to the '517 reference could possibly be *material* as a matter of law because, *as Plaintiffs concede*, the examiner's citation to the '517 reference was itself an error. *Id.* ¶¶ 168, 185 (admitting that the "correct reference" "should have been [] Kyle (2001)"). As Plaintiffs also concede, it was Celgene that brought this error to the attention of the examiner (both in its submission and by telephone)—undermining any notion of a specific intent to deceive—and the examiner confirmed the mistake and withdrew his rejection of the patent claims on the basis of the '517 reference. *Id.* ¶¶ 169, 184. The incorporated record makes all of this plain, starting with Celgene's December 2010 submission, which pointed out that the reference the examiner was relying on could not possibly have been the '517 reference because

[14] The highlighted text sets forth the pleaded chemical name for pomalidomide. Am. Compl. ¶ 76.

the page numbers did not line up. Celgene called the examiner to confirm, and the examiner agreed with "the misplacement of the reference":

> However, there are no abstract, pages 586 and 587 in the '517 Patent (the primary reference) that disclose the treatment of multiple myeloma with thalidomide and dexamethasone, much less the cyclical treatment, as the PTO alleges is disclosed in the primary reference. (*See* page 5 of the Action). Thus, the primary reference is misplaced. For this reason alone, the rejection fails. Applicant respectfully requests that the rejection be withdrawn. [1]
>
> [1] Applicant called the Examiner to clarify the reference. The Examiner admitted the misplacement of the reference and stated that he would withdraw the Office Action. However, Applicant has not received Notice of Withdrawal of the Office Action yet.

Ex. D, at 79. Next, when the examiner withdrew the rejection of the patent in response to Celgene's December 2010 submission, the examiner articulated his specific basis for doing so:

> ***Response to Arguments***
>
> Applicant's arguments, see page 7, 2nd full paragraph, filed 12/23/2010, with respect to the rejections of the claims under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Ex. D, at 90. The paragraph of "Applicant's arguments" that the examiner referenced is the same excerpt above wherein Celgene pointed out that the examiner was discussing a different reference. *Compare* Ex. D, at 90, *with* Ex. D, at 79. In other words, it is undisputed that the examiner withdrew his reliance on the '517 reference because he had not meant to cite it at all—*not* because of the statement elsewhere in Celgene's December 2010 submission that Plaintiffs attack.

It is presumably because the examiner memorialized—in a record that has been public for almost fifteen years—that *he did not rely* on the statement Plaintiffs claim was false, that in this section of their Amended Complaint, Plaintiffs do not even bother to allege *reliance* regarding the

'517 reference. *See* Am. Compl. ¶¶ 168-74 (operative paragraphs nowhere alleging reliance). But their claim fails at the threshold without reliance. *In re DDAVP*, 585 F.3d at 692. This means, as a matter of law, that nothing else that Celgene said in response to a rejection and reference *that was withdrawn by the examiner as a mistake—i.e.*, statements that were *explicitly not relied upon*—could possibly be material to the '262's claims as issued.

*Fourth*, Plaintiffs fail to plead materiality for an additional, independent reason. Plaintiffs concede that the same information that Celgene purportedly withheld from the examiner about the '517 reference *was in two other patents disclosed to the examiner*. *See* Am. Compl. ¶ 123 ("Like the '517, the '230[] and the '554 both publicly disclosed that pomalidomide can be used to reduce TNFα."); *see also* Ex. D, at 46-47 (reflecting that the '230 and '554 were both disclosed to the examiner). The examiner reached the same conclusion. *See* Ex. D, at 62-65. In other words, the very information that was purportedly withheld was concededly cumulative. *Exergen*, 575 F.3d at 1329-30.

***Davies 2001.*** Plaintiffs allege that Celgene made a misrepresentation about this second reference by confirming the examiner's purported misconception about what it disclosed. According to Plaintiffs, the examiner was wrong to believe that the Davies 2001 publication did not disclose the use of pomalidomide to treat multiple myeloma. Am. Compl. ¶ 175. But as Plaintiffs concede, the publication referred only to anonymous compounds, *i.e.*, it did not refer to them by chemical name or structure. *Id.* As a matter of law, the examiner was correct to conclude that the mention in Davies 2001 of only unknown aliases, rather than any chemical name or chemical structure, means that the publication did not disclose *any* compounds, much less pomalidomide. *See Janssen Prods., L.P. v. Lupin, Ltd.*, 109 F. Supp. 3d 650, 689 (D.N.J. 2014) (a reference disclosing only an alias "does not permit any third party to know the compound's

chemical structure" and "provides no relevant information to one of skill in the art" and acknowledging that this sort of nomenclature is common in the pharmaceutical industry). This legal principle is exactly what Celgene argued to the examiner:

> with dexamethasone and cyclic treatment. Davies merely discloses that the compounds studied are thalidomide, and 3 other IMiDs® or immunomodulatory compounds (IMiD1, IMiD2 and IMiD3).[2] *See*, page 212. Without identifying thalidomide analogs by their chemical structures or chemical names, Davies used the general terms, IMiD1, IMiD2, and IMiD3 to identify the compounds. In fact, the Office admits that the secondary reference does not teach ACTIMID. (Page 6 of the Action).

Ex. D, at 80. A correct statement of law obviously cannot constitute a plausibly pleaded fraud.

Moreover, Plaintiffs again fail to allege how *anything* in the December 2010 submission concerning Davies 2001 was material to the patent claims of the '262 patent that ultimately issued.

***D'Amato 2001.*** Plaintiffs allege that Celgene's December 2010 submission should have cited this third reference. Am. Compl. ¶¶ 178-79. But the record demonstrates that Celgene had *already cited* D'Amato 2001 to the examiner:

| | | |
|---|---|---|
| | C03 | Craig et al., 1967, "Potential anticancer agents. III. 2-phthalimidoaldehydes and derivatives," Potential Anticancer Agents III 10:1071-1073 |
| | C04 | D'Amato et al., 2001, "Mechanism of action of thalidomide and 3-aminothalidomide in multiple myeloma," Semin. Oncol. 28:597-601 |
| | C05 | D'Amato et al., 1994, "Thalidomide is an Inhibitor of Angiogenesis", Proc. Natl. Acad. Sci. 91:4082-4085 |

*See* Ex. D, at 48. This disclosure precludes any finding of an *omission* (material, fraudulent, or otherwise). *Fiskars*, 221 F.3d at 1327; *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1366 (Fed. Cir. 1998) (no fraud as a matter of law based on theory that patentee "should have flagged this document and described its significance to the examiner"); *Knauf Insulation, LLC v. Johns Manville Corp.*, 2020 WL 2840024, at *3 (S.D. Ind. June 1, 2020) ("[T]he materials at issue appear on the disclosure list" and so weren't "withheld"). Federal patent law presumes that "the [e]xaminer did his duty and knew what claims he was allowing" over the references Celgene cited. *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1323 (Fed. Cir. 1999) (cleaned up); *Semiconductor*

*Energy Lab'y Co. v. Samsung Elecs. Co.*, 749 F. Supp. 2d 892, 904 (W.D. Wisc. 2010) (patentee had no "obligation to emphasize [the] importance" of a reference it disclosed). Accordingly, these allegations also fail to state a claim for fraud.

b) Celgene's December 2011 Submission.

Plaintiffs next attack purported misstatements in Celgene's December 2011 submission concerning scientific literature. Am. Compl. ¶¶ 187-89. As to each, Plaintiffs fail not only to identify a *specific* misstatement but also to explain how any such statement was material to any claim of the '262 patent.

Plaintiffs first assert that Celgene "misrepresented that the treatment of multiple myeloma with pomalidomide had not been publicly disclosed previously." *Id.* ¶ 187 & n.72. This disclosure, they say, was "fully encompassed" within the same D'Amato 2001 publication discussed above, and in four other references Plaintiffs identify. *Id.* ¶ 187. This allegation fails to state a claim.

*First*, the incorporated record reflects *no representation* about the five references Plaintiffs cite. Instead, as Plaintiffs admit, Celgene's statement to the examiner was *unambiguously constrained* only to specific references (*not the five that Plaintiffs cite*) discussed by the examiner:

> Moreover, irrespective of mechanisms, there is no suggestion in the cited art that pomalidomide is effective to treat multiple myeloma, and no suggestion to combine it with dexamethasone. The Office admits that Davies does not teach pomalidomide (page 4 of the Action). Davies merely discloses that the compounds studied are thalidomide, and 3 other IMiDs® or immunomodulatory compounds (IMiD1, IMiD2 and IMiD3). See, page 212. Without identifying thalidomide analogs by their chemical structures or chemical names, Davies used the general terms, IMiD1, IMiD2, and IMiD3 to identify the compounds.

Ex. D, at 105; *see also* Ex. D, at 104 (same); Am. Compl. ¶ 187 n.72 (same). The examiner did not cite or discuss any of the five references that Plaintiffs now identify, and Celgene's response to him *was only regarding* "the cited art," rather than the five Plaintiffs point to now. Plaintiffs have not plausibly alleged that Celgene made *any representation*, much less a *fraudulent*

*misstatement*, about the meaning of the five references that are the focus of Plaintiffs' present claim.

*Second*, to the extent Plaintiffs allege Celgene fraudulently *omitted* these five references (which they do not clearly do), Plaintiffs ignore that Celgene cited four of them. *Compare* Am. Compl. ¶ 187 (implying that D'Amato 2001, Lentzsch 2001, Lentzsch 2002, and Schey April 2002 were withheld), *with* Ex. D, at 48, 53, 54 (reflecting that each was disclosed). Plaintiffs' failure to accurately depict the prosecution history record that they claim reveals some massive fraud speaks volumes about the liberties taken throughout the Amended Complaint. With respect to the one remaining reference that Plaintiffs suggest was not cited—Schey October 2002—there is no plausible allegation (or allegation *at all*) that it was not cumulative of the four references described above, *or the other 350 references disclosed to the examiner in connection with the '262 patent*. *See Exergen*, 575 F.3d at 1329 (plaintiffs must allege "'why' the withheld information is material and not cumulative"). Nor could Plaintiffs so plead: Plaintiffs themselves assert that the same information in those references was "*fully encompassed*" within D'Amato 2001, Am. Compl. ¶ 187, which Celgene *did* disclose, *see* Ex. D, at 48; *see also Rothman*, 556 F.3d at 1326.

Beyond that, Plaintiffs vaguely refer to "misleading statements," "material omissions" and "misrepresented . . . results" in Celgene's December 2011 submission. Am. Compl. ¶¶ 188-89. But Plaintiffs do not articulate any specific "statement," "omission," or "result." These are conclusions, not plausible allegations. Any claim for fraud—on patents or otherwise—fails when it does not identify, with the specificity required by Rule 9(b), the allegedly fraudulent statement. *See Exergen*, 575 F.3d at 1327. Nor do Plaintiffs even *attempt* to explain how any such misstatement (whatever it might have been) was material, such that had it not been made, specific claims in the '262 would not have issued. *In re DDAVP*, 585 F.3d at 692.

c) Celgene's March 2012 Phone Interview.

Plaintiffs refer to a March 2012 telephone interview between Celgene and the examiner. Am. Compl. ¶¶ 191-92. Plaintiffs again do not identify *any statement or omission* that Celgene made to the examiner, let alone allege how any such statement or omission was material. Instead, Plaintiffs cite and discuss only the examiner's written summary of the interview, which does not reflect any statement by Celgene. *See id.* Plaintiffs' vague reference to the interview does not state any claim for fraud.

***c. The '428 and '3939 method-of-treatment patents.***

Plaintiffs' allegations regarding the two additional method of treatment patents—the '428 and the '3939—also fail on their face.[15] Plaintiffs claim Celgene committed fraud in two ways: first, by submitting a purportedly misleading declaration by Dr. Anjan Thakurta, who Plaintiffs say was not sufficiently qualified; and second, by allegedly "reiterat[ing] many of the same fraudulent misrepresentations and omissions it made" to obtain the '262 patent.[16] Am. Compl. ¶¶ 223-27, 229. Plaintiffs again fail to plead a material misrepresentation or omission, and so fail to plausibly plead fraud.

*First*, Plaintiffs' denigration of Dr. Thakurta, then Celgene's Senior Director of Translational Development for Multiple Myeloma, and before that a post-doctoral fellow at Harvard and at the National Cancer Institute, as unqualified to offer an opinion "on the matters set forth in his declaration," *see* Am. Compl. ¶ 225, fails to state a claim. Dr. Thakurta opined that the results of clinical studies for treating certain types of multiple myeloma with pomalidomide were surprising to him. Ex. E, at 67. The examiner was provided with Dr. Thakurta's *curriculum*

[15] Plaintiffs present one set of allegations as to both patents, Am. Compl. ¶ 221, so they are addressed together here.

[16] These latter allegations are insufficient for the reasons just discussed, *see* Section II.B.1.b, *supra*, and doubly so here because Plaintiffs do not bother to connect those statements to any issued claims of the '428 and '3939 patents.

*vitae* (Ex. E, at 68-75), and there is no allegation *anywhere* that Dr. Thakurta lied about his credentials or omitted any relevant information from them. Plaintiffs do not even attempt to identify a single misstatement or omission as to his qualifications and so cannot fashion a fraud claim on the basis of their unsupported *ad hominem* attack.

*Second*, and in any event, that Dr. Thakurta found the results of his experiments surprising *is not a statement of fact* and cannot sustain a fraud claim. As Plaintiffs concede, and as reflected in the public record, Dr. Thakurta offered his *opinion* about the study results:

> 8. It is therefore my opinion that the results of the studies for treating relapsed and/or refractory multiple myeloma with single-agent pomalidomide would have been unexpected and surprising at the time the claimed invention was made.

Ex. E, at 67; Am. Compl. ¶ 226. An opinion that experimental results were "surprising" does not, as a matter of law, "support a . . . fraud claim." *UFCW v. Novartis Pharms. Corp.*, 2017 WL 2837002, at *15 (D. Mass. June 30, 2017), *aff'd*, 902 F.3d 1 (1st Cir. 2018); *see also UFCW*, 902 F.3d at 11 ("[P]laintiffs have not shown that Novartis's characterization of the existence of the crystalline form of that salt as 'surprising' was anything more than an assertion of nonobviousness," which "is not in and of itself a material misrepresentation for purposes of *Walker Process*.").

*Third*, Plaintiffs fail to adequately allege materiality. Even if Dr. Thakurta's opinion that results were "surprising" can plausibly be pleaded correct or not as a matter of fact (and it cannot), Plaintiffs nowhere plead how or why the examiner would have rejected the specific claims that issued in either patent had the declaration not been submitted. *See UFCW*, 2017 WL 2837002, at *15 ("Plaintiffs have not sufficiently alleged that if [the applicant] had avoided using the word 'surprising,' the patent would not have issued in light of the relevant prior art.").

*Fourth*, to whatever extent Plaintiffs allege Dr. Thakurta was obligated to address certain scientific references in offering his opinion, *see* Am. Compl. ¶ 227 n.84, that allegation fails to state a fraud claim. Most of the references Plaintiffs now identify were, once again, cited to the examiner,[17] and Plaintiffs nowhere plead that Dr. Thakurta *knew any of those references existed* (a required element of any fraud claim), much less how the two sources Celgene did not cite to the examiner contained disclosures unique (*i.e.*, non-cumulative) among the several hundred references Celgene did cite. Plaintiffs simply cannot plausibly plead that Celgene's or Dr. Thakurta's failure to cite or discuss the references Plaintiffs identify establishes but-for materiality. *See Exergen*, 575 F.3d at 1329-30; *Signify N. Am. Corp. v. Reggiani Lighting USA, Inc.*, 2020 WL 1331919, at *6 (S.D.N.Y. Mar. 23, 2020) (requiring knowledge of reference and its materiality).

**2. Plaintiffs fail to plausibly allege that Celgene's formulation patents were acquired via fraud.**

Plaintiffs attack three patents related to formulations of pomalidomide: the '427, '467, and '5939. Celgene filed the first of these applications in 2010; they issued between 2014 and 2020; and the last of them expires in 2031. Am. Compl. ¶ 201. Plaintiffs' various claims of purported fraud in the issuance of these patents fail to state a claim as a matter of law.

***a. The '427 formulation patent.***

Plaintiffs challenge two interactions between Celgene and the examiner as it relates to the '427 patent. First, Plaintiffs allege fraud in Celgene's failure to cite a single scientific reference—Schey April 2002—to the examiner. Am. Compl. ¶ 210. Second, Plaintiffs attack a declaration submitted by Anthony Tutino—then Celgene's Executive Director of Global Pharmaceutical Development and Technology—on the grounds that Tutino (i) relied on undated data to support

[17] Celgene cited Hideshima 2000, Dimopoulous 2001, Davies 2001, and Schey April 2002. Ex. E, at 82, 85, 88, 92.

his opinion of unexpected results; and (ii) allegedly misled the examiner about what was known in the art at the time about pomalidomide's "stability." *Id.* ¶¶ 213-14. These allegations do not state a claim for fraud.

*First*, as to the Schey publication dated April 2002, Plaintiffs nowhere allege with specificity the *materiality* of this reference to the issued patent claims. Plaintiffs insist it disclosed "a maximum tolerated dosage [for pomalidomide] of 5 mg per day." *Id.* ¶ 210. Missing, however, is an allegation of how that supposed disclosure about maximum tolerable dose has *anything* to do with the claims of the '427 patent. To plead fraud, Plaintiffs must at the threshold identify the particular patent "claims, and which limitations in those claims," that was so facially obvious in view of the uncited reference that the failure to cite it was fraudulent. *Exergen*, 575 F.3d at 1329. But Plaintiffs do not plead how Schey April 2002 would have been used by the examiner "in assessing the patentability of the claims," or which specific claims of the '427 patent the examiner would have rejected. *Exergen*, 575 F.3d at 1329-30. Celgene had "no obligation to present the examiner with information that is not material to patentability," *Hupp v. Siroflex of Am., Inc.*, 122 F.3d 1456, 1466 (Fed. Cir. 1997), and Plaintiffs omit any allegation as to why Schey April 2002 *was* material, much less that anyone at Celgene *knew* as much, *see Signify*, 2020 WL 1331919, at *6. And in any event, Plaintiffs do not plead what was disclosed in Schey April 2002 that was not disclosed in the examiner's cited source—an earlier Celgene patent application—which the examiner acknowledged "taught that pomalidomide may be administered in an amount from about 0.1 mg *to about 5 mg per day*." Ex. F, at 27 (emphasis added); *see also Rothman*, 556 F.3d at 1326.

*Second*, whether the data Tutino relied on in his declaration was "undated" is immaterial as a matter of law. Even data "obtained after the patent's filing or issue date" are relevant and

properly considered by the examiner. *See Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1307 (Fed. Cir. 2011). Plaintiffs' counsel are well familiar with this black letter rule: they conceded it and withdrew their argument to the contrary in a hearing in another court in September 2023, before they filed this Amended Complaint.[18] Claiming "fraud" on the basis of a misstatement of patent law falls well below the Rule 9(b) threshold.

Plaintiffs also summarily assert that Tutino submitted "false" data to the examiner. Am. Compl. ¶ 212. Plaintiffs do not even attempt to allege how or why the data is "false." This conclusory assertion about Tutino's declaration does not meet the Rule 9(b) standard and states no claim for fraud. *See, e.g.*, *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 290 (2d Cir. 2006) ("[I]n order to comply with Rule 9(b), the complaint must[ ] specify the statements that the plaintiff contends were fraudulent . . . and . . . explain why the statements were fraudulent.").

***b. The '467 and '5939 formulation patents.***

Plaintiffs again allege that Celgene submitted declarations by Tutino during prosecution of the '467 and '5939 patents that "falsely state[d that] the stability results are surprising and unexpected." *See* Am. Compl. ¶¶ 241, 270. These allegations fail for the reasons described *supra*.

Plaintiffs also do not, and cannot, plead that Tutino's declarations were material to the claims that ultimately issued in the '467 or '5939 patents: the examiner expressly declined to agree with Celgene's argument of unexpected results in evaluating (and ultimately issuing) those patents, including by disagreeing with the very statement that Plaintiffs say was false. *See* Ex. G, at 50 ('467); Ex. G, at 53 ('5939); *see also* Am. Compl. ¶ 270 (admitting the same as to the '5939).

[18] *See In re Revlimid & Thalomid Antitrust Litig.*, No. 2:19-cv-7532-ES, ECF 252, at 159-60 (D.N.J. Sept. 15, 2023) (conceding that *Genetics*, which allows the use of evidence that postdates the application date, is "good authority").

Thus, not only do Plaintiffs fail to *plead* but-for materiality, the public record affirmatively *disproves* it.

* * *

For these reasons, Plaintiffs have not adequately pled a *Walker Process* fraud claim as to any of the six pomalidomide patents that they challenge. Plaintiffs fail to identify a material misstatement or omission that, if not made, would have resulted in the examiner refusing to grant any specific claims. Instead, Plaintiffs offer only conclusory and unsupported statements—not to mention, allegations flatly inconsistent with the record incorporated into their Amended Complaint—to suggest that Celgene defrauded the PTO. The Court should dismiss these plainly deficient claims.

**C. Plaintiffs Fail to Plausibly Plead Sham Litigation.**

Before courts permit the mere filing of a lawsuit suit to trigger antitrust liability, the antitrust plaintiff must plausibly plead, *inter alia*, that the suit was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 59 (2d Cir. 2016) (cleaned up). Such a claim is "construed narrowly so as to avoid intrusion upon, or a chilling of, one's right to petition under the First Amendment," and "properly places a heavy thumb on the scale in favor of the defendant." *In re Elysium Health-Chromadex Litig.*, 354 F. Supp. 3d 330, 336 (S.D.N.Y. 2019).

Because the underlying cases here were patent infringement actions brought under the Hatch-Waxman Act, the standard to plead them "shams" is *even higher*. Plaintiffs must first overcome the fact that all of the patents Celgene asserted in these cases were presumed valid. *See* 35 U.S.C. § 282(a); *see also Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d 1338, 1345 (Fed. Cir. 2014) ("Given the presumption of patent validity . . . , it will be a rare case in which a patentee's assertion of its patent in the face of a claim of invalidity will be so unreasonable as to

support a claim that the patentee has engaged in sham litigation."). That presumption is the reason why, in those cases, the generics faced a "clear and convincing evidence" burden to invalidate the patents. *Berkheimer*, 881 F.3d at 1368.

Finally, where, as here, the accused infringer files an ANDA borrowing the patentee's data but challenging its patents with a so-called Paragraph IV certification, the patentee necessarily has "an objectively reasonable basis to sue." *AstraZeneca AB v. Mylan Lab'ys, Inc.*, 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010), *aff'd sub nom. In re Omeprazole Pat. Litig.*, 412 F. App'x 297 (Fed. Cir. 2011). "[A] reasonable plaintiff in a Hatch-Waxman case would be expected to know few details about the accused product at the outset of litigation and plaintiff's counsel may reasonably rely on discovery to learn the material details." *Id.*

**1. Because every challenged lawsuit ended in a positive outcome for Celgene, they were not objectively baseless as a matter of law.**

Plaintiffs' sham litigation claim runs aground at the threshold: every suit challenged here reached a settlement and consent judgment that preserved the viability and validity of Celgene's patents and allowed Celgene to retain a significant portion of its patent rights—the cases began to settle in 2019, for licenses to the patents beginning in 2026, on patents that expired in 2031.[19]

Courts in this Circuit and throughout the country routinely confirm that settlement of a suit is a favorable outcome such that the suit cannot be sham. *See In re Elysium*, 354 F. Supp. 3d at 338 ("settlement of a purportedly objectively baseless lawsuit" is a "favorable outcome" that "insulates the activity from application of the sham exception"); *Mover's & Warehousemen's Ass'n of Greater N.Y., Inc. v. Long Island Moving & Storage Ass'n, Inc.*, 1999 WL 1243054, at *6 (E.D.N.Y. Dec. 16, 1999) (settlement inconsistent with objective baselessness); *Theme*

[19] As set forth *infra*, Section II.C.2.b, additional patents issued on polymorphic forms of pomalidomide that did not expire until 2037.

*Promotions, Inc. v. News Am. Mktg. FSI*, 546 F.3d 991, 1008 (9th Cir. 2008) (similar); *New W., L.P. v. City of Joliet*, 491 F.3d 717, 722 (7th Cir. 2007) (similar); *cf. Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J.) ("It is not 'bad faith' to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to settle the suit to avoid risking the loss of the rights."), *dismissed*, 104 F. App'x 178 (Fed. Cir. 2004); *see also AstraZeneca AB*, 2010 WL 2079722, at *5 ("[S]uits against [] generic manufacturers of omeprazole were not objectively baseless because they succeeded[.]").

The settlements here provided Celgene nearly all it sought: a judicial declaration on the status of its patent rights and retention of a substantial portion of those rights. The settlements reflect and confirm Plaintiffs' inability to plausibly plead that any one of the patent suits, much less every single one of them, was so baseless "that no reasonable litigant could realistically expect success on the merits." *Apotex*, 823 F.3d at 59. That is why Plaintiffs press circular and nonsensical theories that three of the settlements somehow "paid off" three of those generics—from Plaintiffs' perspective, the best defense (to the favorable settlements of the patent suits) is to conjure an offense (that the favorable outcome was the result of "pay offs"). Plaintiffs state no claim for unlawful settlements (Section I, *supra*), and no claim for "sham litigation" either.

**2. Plaintiffs do not plausibly plead that Celgene's patents were obviously invalid or plainly not infringed.**

Even apart from the settlements, Plaintiffs fail to plausibly plead that Celgene's pomalidomide patents were "obviously invalid" or "plainly not infringed" at the outset of the litigation such that no reasonable litigant would assert them. *Globetrotter Software, Inc. v. Elan Comput. Grp.*, 362 F.3d 1367, 1375 (Fed. Cir. 2004); *Skyline Steel, LLC v. PilePro, LLC*, 2015 WL 3739276, at *3 (S.D.N.Y. June 15, 2015); *Twin City Bakery*, 207 F. Supp. 2d at 223 (alleged sham lawsuit evaluated by looking to the complaint at the time it was filed).

***a. Allegations regarding method-of-treatment and formulation patents.***

Plaintiffs' allegations regarding Celgene's method-of-treatment and formulation patent infringement litigations fail to plausibly plead sham. *First*, Plaintiffs' sham claim is just derivative of their claim that those six patents were unenforceable—and thus objectively baseless to assert in litigation—because they were allegedly procured by fraud. *See, e.g.*, Am. Compl. ¶¶ 253-57, 275, 295-96. As explained, Plaintiffs' allegations of fraud are insufficient. *See* Section II.B, *supra*.

*Second*, Plaintiffs seek to relitigate several theories of invalidity that were addressed during the prosecution of Celgene's patents before the patent examiner. But issued patents are entitled to a strong presumption of validity, particularly with respect to issues addressed with the examiner during prosecution. *Al-Site Corp.*, 174 F.3d at 1323; *see also Sanofi-Synthelabo v. Apotex Inc.*, 492 F. Supp. 2d 353, 381-82 (S.D.N.Y. 2007). This gave Celgene even more than a reasonable expectation of success over Plaintiffs' invalidity theories—it gave Celgene a *presumption* that its patents were valid over those theories. *UFCW*, 2017 WL 2837002, at *11 (rejecting attempt by Louisiana Health to relitigate impact of references presented to examiner). That Plaintiffs wish the examiners would have reached different conclusions and not issued the patents does not plead that Celgene's assertion of those patents was a sham.

*Third*, Plaintiffs allege that the generics "would" have had arguments their products did not infringe Celgene's presumptively valid patent claims and "could" have designed around those claims. *E.g.*, Am. Compl. ¶¶ 218, 245, 251, 256, 272. This is not a pleading of sham litigation: allegations that Plaintiffs (or the generics) "disagreed with the arguments [Celgene] advanced" are insufficient as a matter of law to establish that Celgene's litigation "was a sham." *Apotex*, 823 F.3d at 61; *see also AbbVie*, 42 F.4th at 712-13 (not an antitrust violation to assert allegedly "weak" patents). Indeed, even had Celgene lost the patent litigations, that would not demonstrate objective

baselessness as of the time they were filed. *Apotex*, 823 F.3d at 61 (antitrust plaintiff "elide[d] the distinction between arguments that fail . . . and arguments that are false and objectively baseless").

Plaintiffs fail to allege anything *at all* about how an objectively reasonable litigant at the time the suits were initiated would *know* that the generics would not infringe Celgene's patent claims based on the information in the generics' Paragraph IV notices. Celgene had forty-five days after receiving such notices to file suit to protect and assert its patent rights. *See* 21 U.S.C. § 355(j)(5)(B)(iii). This limits any patentee's ability to evaluate the nuances of each proposed generic product, something that is intentional under the Hatch-Waxman Act's "file-now, discover-details-later policy." *Takeda Pharm. Co. Ltd. v. Zydus Pharms. (USA) Inc.*, 2022 WL 17546949, at *3 n.5 (3d Cir. Dec. 9, 2022) (explaining that a brand cannot know every detail about a generic drug before it is required to file suit under the Hatch-Waxman Act); *see also AstraZeneca AB*, 2010 WL 2079722, at *4 (Paragraph IV certification provides a reasonable basis to sue). But again, even years later, Plaintiffs plead no specifics about how any particular generic actually designed a non-infringing product—simply to say it does not adequately plead it.

*Fourth*, though Plaintiffs claim Celgene's suits endured a "series of blows," ECF 98, at 3, they cite only the result of a single decision during the challenged litigations—an interim ruling construing disputed claim terms in the method-of treatment patents and the '427 patent—where the court ruled for the generics on a single disputed term. Am. Compl. ¶ 301. As an initial matter, Celgene was not required to "divine the outcome of claim construction before filing." *In re Wellbutrin*, 868 F.3d 132, 151 n.22 (3d Cir. 2017). And Plaintiffs omit that the same decision *ruled for Celgene on other disputed claim terms*. *Celgene*, 2020 WL 3249117, at *4-12. There is no plausible way for Plaintiffs to conclusorily characterize the court's decision as indicating that all of Celgene's patent suits were objectively baseless, much less that they were baseless at the

time they were filed three years earlier. *See, e.g.*, *AstraZeneca AB*, 2010 WL 2079722, at *4 ("[T]he Court ruled that Astra had proven that two of three contested limitations of its claims . . . were found in Mylan's product. . . . This outcome hardly bespeaks baseless litigation.").

***b. Allegations regarding Celgene's polymorph patents.***

Plaintiffs also brand as a sham Celgene's assertion in litigation three patents that cover crystalline forms of pomalidomide: the '647, '648, and '649 (collectively, the "polymorph patents"). Celgene filed the first of these applications in 2017; they issued between 2018 and 2020; and the last of them expires in 2037. Am. Compl. ¶ 262. Plaintiffs do not claim any fraud in the issuance of these patents; their sham litigation claim fails, too.

Plaintiffs contend that Celgene applied for, and received, these patents after receiving Paragraph IV certifications from the generics here. Am. Compl. ¶¶ 262-66. That, say Plaintiffs, trapped Celgene in some kind of Catch-22: if the generics' products "infringed" these patents, then these later-in-time polymorph patents were invalid because the polymorphs were purportedly disclosed by the generics prior to the patents being applied for; whereas, if the polymorph patents *weren't* invalid, then the generics' products could not have infringed. *Id.* ¶¶ 282-84.

*First*, Plaintiffs fail to plead any particular disclosure in the Paragraph IV letters that rendered Celgene's polymorph patents invalid. Without any particular invalidating prior art disclosure to point to, Plaintiffs have no basis whatsoever to conclude that no reasonable litigant could believe Celgene's patents valid; but that is the burden Plaintiffs face in seeking to circumvent *Noerr-Pennington* immunity. *Apotex*, 823 F.3d at 59.

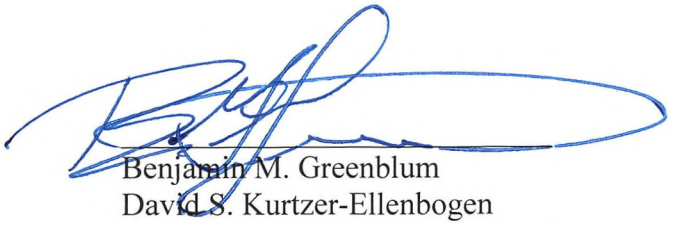
*Second*, Plaintiffs refer in passing to the generics' ANDA products, *see* Am. Compl. ¶ 283, but they do not allege that Celgene had access to the generics' ANDA products, or that Celgene had access to the generics' submissions to the FDA concerning such products (other than what is described in the Paragraph IV letters). 21 C.F.R. § 314.430(b) (FDA will not disclose ANDA until

it is approved); *La. Wholesale Drug Co. v. Sanofi-Aventis*, 2008 WL 4580016, at *1 (S.D.N.Y. Oct. 14, 2008) (FDA must "keep the existence and contents of ANDAs confidential unless and until [it] approves them, thus Defendants could anticipate, but could not know . . . what [generic manufacturers] would request in their application."). Nor is it uncommon for generics to face infringement claims on patents that issued after the generics filed their ANDAs. *E.g.*, *Rsch. Found. of State Univ. of N.Y. v. Mylan Pharms. Inc.*, 2012 WL 1901267, at *5 (D. Del. May 25, 2012) (granting injunction in a Hatch-Waxman case on a patent that issued over a year after the generic's ANDA was filed).

Plaintiffs likewise fall short with their conclusory allegation that Celgene "could not succeed" in proving infringement of its polymorph patents. Am. Compl. ¶ 284. Plaintiffs do not allege *why* this was impossible, *how* Celgene would have known this was impossible, or any detail *whatsoever* about the generic product such that it was, *in fact* impossible. These unsupported conclusions fail to plead that Celgene's litigations were all shams.

## CONCLUSION

Plaintiffs believe they've unearthed a scheme to monopolize. But their Amended Complaint alleges only routine interactions with the PTO, run of the mill lawsuits to protect issued patents, and unassailable settlements of those litigations. Despite amending, Plaintiffs have failed to plead actionable violations of the antitrust laws. The Court should dismiss with prejudice.



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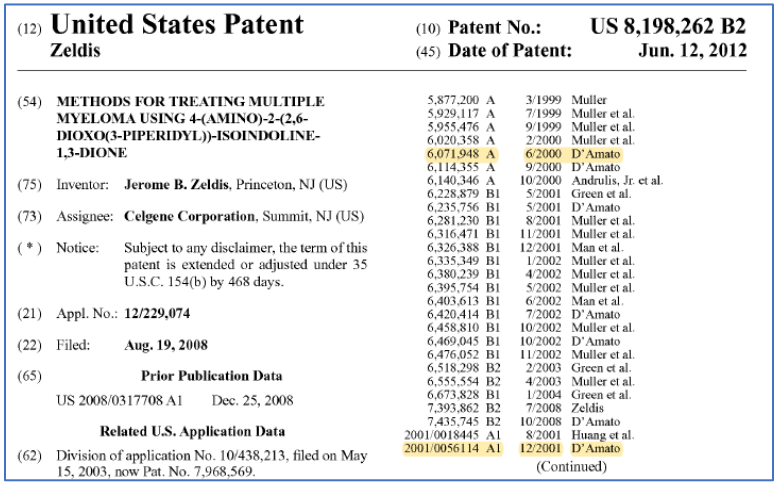
# APPENDIX 1

## D'Amato Patent Disclosures

| D'Amato Source Allegedly "Buried" (Am. Compl. ¶¶ 154-55) | '262 Disclosure (*See* Ex. D, at 3-4, 46-47) |
|---|---|
| U.S. Patent No. 7,153,867 | Disclosed as the patent application 2003/0139451 A1 – Shah et al. |
| U.S. Patent App. 09/899,344 | Disclosed as 2001/0056114 A1 – D'Amato |
| U.S. Patent App. 10/166,539 | Disclosed as 2002/0161023 A1 – D'Amato |
| U.S. Patent App. 09/966,895 | Same patent family and substantive disclosure as the 5,629,327 D'Amato patent (disclosed), the 5,712,291 D'Amato patent (disclosed), and the 6,071,948 D'Amato patent (disclosed) |
| U.S. Patent App. 10/020,391 | Same patent family and substantive disclosure as the 5,629,327 D'Amato patent (disclosed), the 5,712,291 D'Amato patent (disclosed), and the 6,071,948 D'Amato patent (disclosed) |

## Disclosures on the face of the '262 Patent (Ex. D, at 3-4):



(12) **United States Patent**
**Zeldis**

(10) **Patent No.: US 8,198,262 B2**
(45) **Date of Patent: Jun. 12, 2012**

(54) **METHODS FOR TREATING MULTIPLE MYELOMA USING 4-(AMINO)-2-(2,6-DIOXO(3-PIPERIDYL))-ISOINDOLINE-1,3-DIONE**

(75) Inventor: **Jerome B. Zeldis**, Princeton, NJ (US)

(73) Assignee: **Celgene Corporation**, Summit, NJ (US)

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 468 days.

(21) Appl. No.: **12/229,074**

(22) Filed: **Aug. 19, 2008**

(65) **Prior Publication Data**

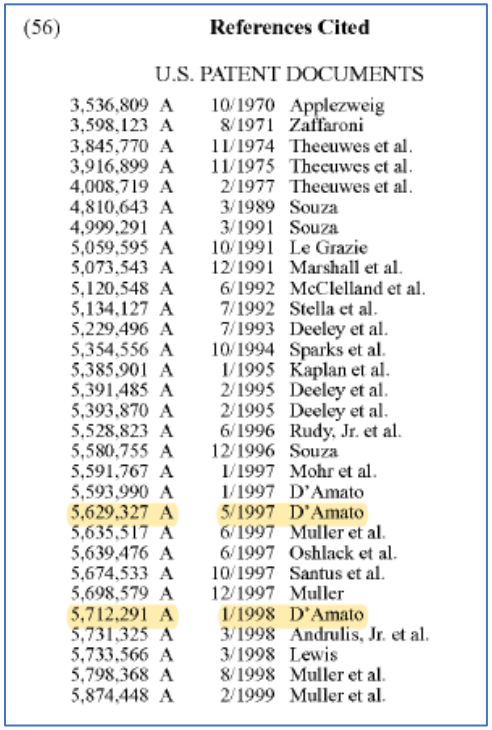
US 2008/0317708 A1 Dec. 25, 2008

**Related U.S. Application Data**

(62) Division of application No. 10/438,213, filed on May 15, 2003, now Pat. No. 7,968,569.

| | | | |
|---|---|---|---|
| 5,877,200 | A | 3/1999 | Muller |
| 5,929,117 | A | 7/1999 | Muller et al. |
| 5,955,476 | A | 9/1999 | Muller et al. |
| 6,020,358 | A | 2/2000 | Muller et al. |
| 6,071,948 | A | 6/2000 | D'Amato |
| 6,114,355 | A | 9/2000 | D'Amato |
| 6,140,346 | A | 10/2000 | Andrulis, Jr. et al. |
| 6,228,879 | B1 | 5/2001 | Green et al. |
| 6,235,756 | B1 | 5/2001 | D'Amato |
| 6,281,230 | B1 | 8/2001 | Muller et al. |
| 6,316,471 | B1 | 11/2001 | Muller et al. |
| 6,326,388 | B1 | 12/2001 | Man et al. |
| 6,335,349 | B1 | 1/2002 | Muller et al. |
| 6,380,239 | B1 | 4/2002 | Muller et al. |
| 6,395,754 | B1 | 5/2002 | Muller et al. |
| 6,403,613 | B1 | 6/2002 | Man et al. |
| 6,420,414 | B1 | 7/2002 | D'Amato |
| 6,458,810 | B1 | 10/2002 | Muller et al. |
| 6,469,045 | B1 | 10/2002 | D'Amato |
| 6,476,052 | B1 | 11/2002 | Muller et al. |
| 6,518,298 | B2 | 2/2003 | Green et al. |
| 6,555,554 | B2 | 4/2003 | Muller et al. |
| 6,673,828 | B1 | 1/2004 | Green et al. |
| 7,393,862 | B2 | 7/2008 | Zeldis |
| 7,435,745 | B2 | 10/2008 | D'Amato |
| 2001/0018445 | A1 | 8/2001 | Huang et al. |
| 2001/0056114 | A1 | 12/2001 | D'Amato |

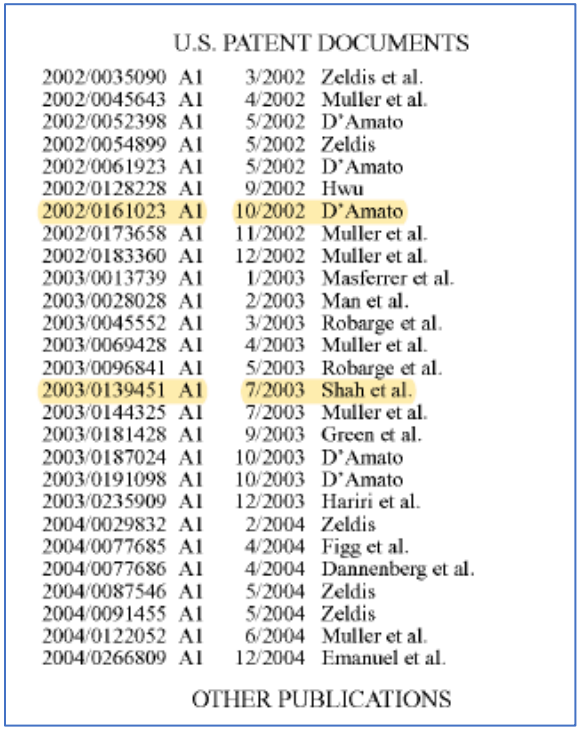
(Continued)



(56) **References Cited**

U.S. PATENT DOCUMENTS

| | | | |
|---|---|---|---|
| 3,536,809 | A | 10/1970 | Applezweig |
| 3,598,123 | A | 8/1971 | Zaffaroni |
| 3,845,770 | A | 11/1974 | Theeuwes et al. |
| 3,916,899 | A | 11/1975 | Theeuwes et al. |
| 4,008,719 | A | 2/1977 | Theeuwes et al. |
| 4,810,643 | A | 3/1989 | Souza |
| 4,999,291 | A | 3/1991 | Souza |
| 5,059,595 | A | 10/1991 | Le Grazie |
| 5,073,543 | A | 12/1991 | Marshall et al. |
| 5,120,548 | A | 6/1992 | McClelland et al. |
| 5,134,127 | A | 7/1992 | Stella et al. |
| 5,229,496 | A | 7/1993 | Deeley et al. |
| 5,354,556 | A | 10/1994 | Sparks et al. |
| 5,385,901 | A | 1/1995 | Kaplan et al. |
| 5,391,485 | A | 2/1995 | Deeley et al. |
| 5,393,870 | A | 2/1995 | Deeley et al. |
| 5,528,823 | A | 6/1996 | Rudy, Jr. et al. |
| 5,580,755 | A | 12/1996 | Souza |
| 5,591,767 | A | 1/1997 | Mohr et al. |
| 5,593,990 | A | 1/1997 | D'Amato |
| 5,629,327 | A | 5/1997 | D'Amato |
| 5,635,517 | A | 6/1997 | Muller et al. |
| 5,639,476 | A | 6/1997 | Oshlack et al. |
| 5,674,533 | A | 10/1997 | Santus et al. |
| 5,698,579 | A | 12/1997 | Muller |
| 5,712,291 | A | 1/1998 | D'Amato |
| 5,731,325 | A | 3/1998 | Andrulis, Jr. et al. |
| 5,733,566 | A | 3/1998 | Lewis |
| 5,798,368 | A | 8/1998 | Muller et al. |
| 5,874,448 | A | 2/1999 | Muller et al. |



U.S. PATENT DOCUMENTS

| | | | |
|---|---|---|---|
| 2002/0035090 | A1 | 3/2002 | Zeldis et al. |
| 2002/0045643 | A1 | 4/2002 | Muller et al. |
| 2002/0052398 | A1 | 5/2002 | D'Amato |
| 2002/0054899 | A1 | 5/2002 | Zeldis |
| 2002/0061923 | A1 | 5/2002 | D'Amato |
| 2002/0128228 | A1 | 9/2002 | Hwu |
| 2002/0161023 | A1 | 10/2002 | D'Amato |
| 2002/0173658 | A1 | 11/2002 | Muller et al. |
| 2002/0183360 | A1 | 12/2002 | Muller et al. |
| 2003/0013739 | A1 | 1/2003 | Masferrer et al. |
| 2003/0028028 | A1 | 2/2003 | Man et al. |
| 2003/0045552 | A1 | 3/2003 | Robarge et al. |
| 2003/0069428 | A1 | 4/2003 | Muller et al. |
| 2003/0096841 | A1 | 5/2003 | Robarge et al. |
| 2003/0139451 | A1 | 7/2003 | Shah et al. |
| 2003/0144325 | A1 | 7/2003 | Muller et al. |
| 2003/0181428 | A1 | 9/2003 | Green et al. |
| 2003/0187024 | A1 | 10/2003 | D'Amato |
| 2003/0191098 | A1 | 10/2003 | D'Amato |
| 2003/0235909 | A1 | 12/2003 | Hariri et al. |
| 2004/0029832 | A1 | 2/2004 | Zeldis |
| 2004/0077685 | A1 | 4/2004 | Figg et al. |
| 2004/0077686 | A1 | 4/2004 | Dannenberg et al. |
| 2004/0087546 | A1 | 5/2004 | Zeldis |
| 2004/0091455 | A1 | 5/2004 | Zeldis |
| 2004/0122052 | A1 | 6/2004 | Muller et al. |
| 2004/0266809 | A1 | 12/2004 | Emanuel et al. |

OTHER PUBLICATIONS